

Date: 4 July 2025

Swissmedic, Swiss Agency for Therapeutic Products

Swiss Public Assessment Report

NEXPOVIO

International non-proprietary name:	Selinexor
Pharmaceutical form:	Film-coated tablet
Dosage strength(s):	20 mg
Route(s) of administration:	Oral
Marketing authorisation holder:	Stemline Therapeutics Switzerland GmbH
Marketing authorisation no.:	69230
Decision and decision date:	approved on 29 April 2025

Note:

This assessment report is as adopted by Swissmedic with all information of a commercially confidential nature deleted.

SwissPARs are final documents that provide information on submissions at a particular point in time. They are not updated after publication.

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1 Terms, Definitions, Abbreviations

1L	First-line
2L	Second-line
ADA	Anti-drug antibody
ADME	Absorption, distribution, metabolism, elimination
AE	Adverse event
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
API	Active pharmaceutical ingredient
ATC	Anatomical Therapeutic Chemical Classification System
AUC	Area under the plasma concentration-time curve
AUC _{0-24h}	Area under the plasma concentration-time curve for the 24-hour dosing interval
CI	Confidence interval
C _{max}	Maximum observed plasma/serum concentration of drug
CYP	Cytochrome P450
DDI	Drug-drug interaction
DOR	Duration of response
ECOG	Eastern Cooperative Oncology Group
EMA	European Medicines Agency
ERA	Environmental risk assessment
FDA	Food and Drug Administration (USA)
GLP	Good Laboratory Practice
HPLC	High-performance liquid chromatography
IC/EC ₅₀	Half-maximal inhibitory/effective concentration
ICH	International Council for Harmonisation
Ig	Immunoglobulin
INN	International non-proprietary name
ITT	Intention-to-treat
LoQ	List of Questions
MAH	Marketing Authorisation Holder
Max	Maximum
Min	Minimum
MRHD	Maximum recommended human dose
MTD	Maximum tolerated dose
N/A	Not applicable
NCCN	National Comprehensive Cancer Network
NO(A)EL	No observed (adverse) effect level
ORR	Objective response rate
OS	Overall survival
PBPK	Physiology-based pharmacokinetics
PD	Pharmacodynamics
PFS	Progression-free survival
PIP	Paediatric Investigation Plan (EMA)
PK	Pharmacokinetics
PopPK	Population pharmacokinetics
PSP	Pediatric study plan (US FDA)
RMP	Risk management plan
SAE	Serious adverse event
Sd	Selinexor plus low-dose dexamethasone
SVd	Selinexor plus bortezomib plus low-dose dexamethasone
SwissPAR	Swiss Public Assessment Report
TEAE	Treatment-emergent adverse event

TPA Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21)
TPO Ordinance of 21 September 2018 on Therapeutic Products (SR 812.212.21)

2 Background information on the procedure

2.1 Applicant's request(s)

New active substance status

The applicant requested new active substance status for selinexor in the above-mentioned medicinal product.

Orphan drug status

The applicant requested orphan drug status in accordance with Article 4 paragraph 1 letter a^{decies} no. 2 TPA.

Orphan drug status was granted on 12 January 2023.

Authorisation as human medicinal product in accordance with Article 13 TPA

The applicant requested a reduced assessment procedure in accordance with Article 13 TPA.

2.2 Indication and dosage

2.2.1 Requested indication

NEXPOVIO is indicated:

- in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.
- in combination with dexamethasone for the treatment of multiple myeloma in adult patients who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.

The applicant withdrew part of the indication initially claimed for Nexpovio in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

2.2.2 Approved indication

NEXPOVIO is indicated in combination with dexamethasone for the treatment of multiple myeloma in adult patients who have received at least four lines of therapy and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.

2.2.3 Requested dosage

Summary of the requested standard dosage:

The target dose for selinexor in combination with bortezomib and dexamethasone (SVd) is 100mg orally once weekly on day 1 of each week.

The recommended dose for selinexor in combination with dexamethasone (Sd 80mg selinexor taken orally on day 1 and 3 of each week.

2.2.4 Approved dosage

(See appendix)

2.3 Regulatory history (milestones)

Application	31 March 2023
Formal objection	19 April 2023
Response to formal objection	14 May 2023
Formal control completed	9 June 2023
List of Questions (LoQ)	6 October 2023
Response to LoQ	22 December 2023
Preliminary decision	21 March 2024
Response to preliminary decision	6 June 2024
Labelling corrections and/or other aspects	10 September 2024
Response to labelling corrections and/or other aspects	8 October 2024
2 nd preliminary decision	19 December 2024
2 nd response to preliminary decision	7 February 2025
Final decision	29 April 2025
Decision	approval

Swissmedic has only assessed parts of the primary data submitted with this application. As regards the remaining data, Swissmedic relies for its decision on the assessment of the foreign reference authority EMA. This SwissPAR relates to the publicly available EMA Assessment Report for Nexpovio, published on 27 May 2021, Procedure No. EMEA/H/C/005127/0000.

3 Medical context

Swissmedic has only assessed parts of the primary data submitted with this application. As regards the remaining data, Swissmedic relies for its decision on the assessment of the foreign reference authority European Medicines Agency (EMA). This SwissPAR relates to the publicly available assessment report Nexpovio published on 27 May 2021, Procedure No. EMEA/H/C/005127/0000 issued by EMA.

4 Quality aspects

Swissmedic has not assessed the primary data relating to quality aspects submitted with this application and relies on the assessment of the foreign reference authority EMA. The SwissPAR relating to quality aspects refers to the publicly available EMA Assessment Report for Nexpovio, published on 27 May 2021, Procedure No. EMEA/H/C/005127/0000

5 Nonclinical aspects

Swissmedic has not assessed the primary data relating to nonclinical aspects submitted with this application and relies on the assessment of the foreign reference authority EMA. The nonclinical aspects in this SwissPAR refer to the publicly available EMA Assessment Report for Nexpovio, published on 27 May 2021, Procedure No. EMEA/H/C/005127/0000.

6 Clinical aspects

Swissmedic has only assessed parts of the primary data submitted with this application. As regards the remaining data, Swissmedic relies for its decision on the assessment of the foreign reference authority European Medicines Agency (EMA). This SwissPAR relates to the publicly available assessment report for Nexpovio published on 27 May 2021, Procedure No. EMEA/H/C/005127/0000 issued by EMA.

7 Risk management plan summary

The RMP summaries contain information on the medicinal products' safety profiles and explain the measures that are taken to further investigate and monitor the risks, as well as to prevent or minimise them.

The RMP summaries are published separately on the Swissmedic website. It is the responsibility of the marketing authorisation holder to ensure that the content of the published RMP summaries is accurate and correct. As the RMPs are international documents, their summaries might differ from the content in the Information for healthcare professionals / product information approved and published in Switzerland, e.g. by mentioning risks that occur in populations or indications not included in the Swiss authorisations.

8 Appendix

Approved Information for healthcare professionals

Please be aware that the following version of the Information for healthcare professionals for Nexpovio was approved with the submission described in the SwissPAR. This Information for healthcare professionals may have been updated since the SwissPAR was published.

Please note that the valid and relevant reference document for the effective and safe use of medicinal products in Switzerland is the Information for healthcare professionals currently authorised by Swissmedic (see www.swissmedicinfo.ch).

Note:

The following Information for healthcare professionals has been translated by the MAH. It is the responsibility of the authorisation holder to ensure the translation is correct. The only binding and legally valid text is the Information for healthcare professionals approved in one of the official Swiss languages.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected new or serious adverse reactions. See the "Undesirable effects" section for advice on the reporting of adverse reactions.

NEXPOVIO, film-coated tablets

Composition

Active substances

Selinexor.

Excipients

Each film-coated tablet contains in the tablet core microcrystalline cellulose (E460i), croscarmellose sodium (E468), povidone K30 (E1201), highly disperse silicon dioxide (E551), magnesium stearate (E470b), Sodium dodecyl sulfate (E514i) and in the tablet coating talc (E553b), poly(vinyl alcohol) (E1203), glyceryl monostearate (E471), polysorbate 80 (E433), titanium dioxide (E171), macrogol 3350 (E1521), Indigotin (E132), brilliant blue FCF (E133).

Each film-coated tablet contains up to 1.028 mg sodium.

Pharmaceutical form and active substance quantity per unit

Each film-coated tablet contains 20mg selinexor

Blue, round, bi-convex, film-coated tablet (4 mm thick and 7 mm in diameter) with "K20" debossed on one side.

Indications/Uses

NEXPOVIO is indicated in combination with dexamethasone for the treatment of multiple myeloma in adult patients who have received at least four lines of therapy and whose disease is refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.

Dosage/Administration

Treatment must be initiated and monitored under supervision of physicians experienced in the management of multiple myeloma.

The recommended selinexor and dexamethasone starting doses are as follows:

- Selinexor 80 mg taken orally on Days 1 and 3 of each week.

- Dexamethasone 20 mg taken orally on Days 1 and 3 of each week with selinexor.

Treatment with selinexor combined with dexamethasone should be continued until disease progression or unacceptable toxicity.

For information regarding the posology of medicinal products administered with NEXPOVIO, refer to the professional information for these medicinal products.

Delayed or missed doses

If a selinexor dose is missed or delayed or a patient vomits after a dose of selinexor, the patient should not repeat the dose. Patients should take the next dose on the next regularly scheduled day.

Dose adjustment following undesirable effects/interactions

Recommended NEXPOVIO dose modifications for adverse reactions are presented in Table 1 and Table 2.

For information regarding dosage modification of medicinal products administered with NEXPOVIO, refer to their corresponding SmPC.

Table 1: Prespecified dose modification steps for adverse reactions

	<i>Selinexor in combination with Dexamethasone (Sd)</i>
Recommended starting dose	80 mg Days 1 and 3 of each week (160 mg total per week)
First reduction	100 mg once weekly
Second reduction	80 mg once weekly
Third reduction	60 mg once weekly
Discontinue*	

* If symptoms do not resolve, treatment should be discontinued

Table 2: Dose modification guidelines for adverse reactions

<i>Adverse reaction^a</i>	<i>Occurrence</i>	<i>Action</i>
Haematologic adverse reactions		
<i>Thrombocytopenia</i>		
Platelet count 25,000 to less than 75,000/ μ l	Any	• Reduce selinexor by 1 dose level (see Table 1).

Product information for human medicinal products

Adverse reaction^a	Occurrence	Action
Platelet count 25,000 to less than 75,000/ μ l with concurrent bleeding	Any	<ul style="list-style-type: none"> • Interrupt selinexor. • Restart selinexor at 1 dose level lower (see Table 1), after bleeding has resolved.
Platelet count less than 25,000/ μ l	Any	<ul style="list-style-type: none"> • Interrupt selinexor. • Monitor until platelet count returns to at least 50,000/ μl. • Restart selinexor at 1 dose level lower (see Table 1).
Neutropenia		
Absolute neutrophil count of 0.5 to 1.0 x 10 ⁹ /l without fever	Any	<ul style="list-style-type: none"> • Reduce selinexor by 1 dose level (see Table 1).
Absolute neutrophil count less than 0.5 x 10 ⁹ /l OR Febrile neutropenia	Any	<ul style="list-style-type: none"> • Interrupt selinexor. • Monitor until neutrophil counts return to 1.0 x 10⁹/l or higher. • Restart selinexor at 1 dose level lower (see Table 1).
Anaemia		
Haemoglobin less than 8.0 g/dl	Any	<ul style="list-style-type: none"> • Reduce selinexor by 1 dose level (see Table 1). • Administer blood transfusions and/or other treatments per clinical guidelines.
Life-threatening consequences (urgent intervention indicated)	Any	<ul style="list-style-type: none"> • Interrupt selinexor. • Monitor haemoglobin until levels return to 8 g/dl or higher. • Restart selinexor at 1 dose level lower (see Table 1). • Administer blood transfusions and/or other treatments per clinical guidelines.
Non-haematologic adverse reactions		
Hyponatraemia		
Sodium level 130 mmol/l or less	Any	<ul style="list-style-type: none"> • Interrupt selinexor and provide appropriate supportive care. • Monitor until sodium levels return to 130 mmol/l or higher. • Restart selinexor at 1 dose level lower (see Table 1).
Fatigue		
Grade 2 lasting greater than 7 days OR Grade 3	Any	<ul style="list-style-type: none"> • Interrupt selinexor. • Monitor until fatigue resolves to Grade 1 or baseline. • Restart selinexor at 1 dose level lower (see Table 1).
Nausea and vomiting		

Product information for human medicinal products

Adverse reaction^a	Occurrence	Action
Grade 1 or 2 nausea (oral intake decreased without significant weight loss, dehydration or malnutrition) OR Grade 1 or 2 vomiting (5 or fewer episodes per day)	Any	<ul style="list-style-type: none"> • Maintain selinexor and initiate additional anti-nausea medicinal products.
Grade 3 nausea (inadequate oral caloric or fluid intake) OR Grade 3 or higher vomiting (6 or more episodes per day)	Any	<ul style="list-style-type: none"> • Interrupt selinexor. • Monitor until nausea or vomiting has resolved to Grade 2 or lower or baseline. • Initiate additional anti-nausea medicinal products. • Restart selinexor at 1 dose level lower (see Table 1).
Diarrhoea		
Grade 2 (increase of 4 to 6 stools per day over baseline)	1 st	<ul style="list-style-type: none"> • Maintain selinexor and institute supportive care.
	2 nd and subsequent	<ul style="list-style-type: none"> • Reduce selinexor by 1 dose level (see Table 1). • Institute supportive care.
Grade 3 or higher (increase of 7 stools or more per day over baseline; hospitalization indicated)	Any	<ul style="list-style-type: none"> • Interrupt selinexor and institute supportive care. • Monitor until diarrhoea resolves to Grade 2 or lower. • Restart selinexor at 1 dose level lower (see Table 1).
Weight loss and anorexia		
Weight loss of 10% to less than 20% OR Anorexia associated with significant weight loss or malnutrition	Any	<ul style="list-style-type: none"> • Interrupt selinexor and institute supportive care. • Monitor until weight returns to more than 90% of baseline weight. • Restart selinexor at 1 dose level lower (see Table 1).
Ocular adverse reactions		
Grade 2, excluding cataract	Any	<ul style="list-style-type: none"> • Perform ophthalmologic evaluation. • Interrupt selinexor and provide supportive care. • Monitor until ocular symptoms resolve to Grade 1 or baseline. • Restart selinexor at 1 dose level lower (see Table 1).

Product information for human medicinal products

Adverse reaction^a	Occurrence	Action
Grade \geq 3, excluding cataract	Any	<ul style="list-style-type: none">• Permanently discontinue selinexor.• Perform ophthalmologic evaluation.
<i>Other non-haematologic adverse reactions</i>		
Grade 3 or 4 (life threatening)	Any	<ul style="list-style-type: none">• Interrupt selinexor.• Monitor until resolved to Grade 2 or lower.• Restart selinexor at 1 dose level lower (see Table 1).

^a National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.03.

Special dosage instructions

Patients with hepatic disorders

No dose adjustment of selinexor is required for patients with mild hepatic impairment (see section “Pharmacokinetics”). There are insufficient data in patients with moderate or serious hepatic impairment to support a dose recommendation.

Patients with renal disorders

No dose adjustment of selinexor is required for patients with mild, moderate, or serious renal impairment (see section “Pharmacokinetics”). There are no data in patients with end-stage renal disease or haemodialysis to support a dose recommendation.

Elderly patients

No dose adjustment of selinexor is required for patients over 65 years of age (see sections “Undesirable effects”, “Properties/effects, Pharmacodynamics” and “Pharmacokinetics”).

Children and adolescents

NEXPOVIO is not indicated in paediatrics.

The safety and efficacy in patients under 18 years have not been demonstrated.

Administration schedule

NEXPOVIO in combination with dexamethasone (Sd) should be taken at approximately the same time on Days 1 and 3 of each week.

Mode of administration

NEXPOVIO is for oral use.

The tablet should be swallowed whole with water. It should not be crushed, chewed, broken, or divided in order to prevent risk of skin irritation from the active substance. It can be taken with or without food.

Contraindications

NEXPOVIO is contraindicated in case of hypersensitivity to the active substance or to any of the excipients.

Warnings and precautions

For medicinal products administered in combination with selinexor, the professional information of these medicinal products must be consulted prior to initiation of treatment, including for special warnings and precaution for use and recommended concomitant treatments.

Recommended concomitant treatments

Patients should be advised to maintain adequate fluid and caloric intake throughout treatment.

Intravenous hydration should be considered for patients at risk of dehydration.

Prophylactic concomitant treatment with a 5-HT₃ antagonist and/or other anti-nausea agents should be provided prior to and during treatment with NEXPOVIO (see section “Undesirable effects”).

Haematology

Patients should have their complete blood counts (CBC) assessed at baseline, during treatment, and as clinically indicated. Monitor more frequently during the first two months of treatment.

Thrombocytopenia

Thrombocytopenic events (thrombocytopenia and platelet count decreased) which can be serious (Grade 3/4) were frequently reported in patients receiving selinexor. Grade 3/4 thrombocytopenia can sometimes lead to clinically significant bleeding and in rare cases may lead to potentially fatal haemorrhage (see section “Undesirable effects”).

Thrombocytopenia can be managed with dose interruptions, modifications, platelet transfusions, and/or other treatments as clinically indicated. Patients should be monitored for signs and symptoms of bleeding and evaluated promptly. For dose modification guidelines refer to Table 1 and Table 2 in section “Dosage/Administration”.

Anaemia

Anaemia including serious anaemia (Grade 3/4) has been reported with selinexor (see section “Undesirable effects”). For dose modification guidelines refer to Table 1 and Table 2 in section “Dosage/Administration”.

Neutropenia

Neutropenia including serious neutropenia (Grade 3/4) has been reported with selinexor. In a few cases concurrent infections occurred in patients with Grade 3/4 neutropenia (see section “Undesirable effects”).

Patients with neutropenia should be monitored for signs of infection and evaluated promptly.

Neutropenia can be managed with dose interruptions, modifications, and colony-stimulating factors as per medical guidelines. For dose modification guidelines refer to Table 1 and Table 2 in section “Dosage/Administration”.

Pneumonia and upper respiratory tract infections

Serious cases of upper respiratory tract infection and pneumonia, including fatal infections have been reported with selinexor (see section “Undesirable effects”). Patients should be closely monitored for signs and symptoms of infection. In the presence of signs of systemic infection selinexor dose modification or discontinuation may be required.

Gastrointestinal toxicity

Nausea, vomiting, diarrhoea, which sometimes can be serious (Grade 3/4) and require the use of anti-emetic and anti-diarrhoeal medicinal products (see section “Undesirable effects”).

Prophylaxis with 5HT3 antagonists and/or other anti-nausea agents should be provided prior to and during treatment with selinexor. Fluids with electrolytes should be administered to prevent dehydration in patients at risk.

Nausea/vomiting can be managed by dose interruptions, modifications, and/or initiation of other antiemetics medicinal products as clinically indicated. Diarrhoea can be managed with dose interruptions, modifications and/or administration of anti-diarrhoea medicinal products. For dose modification guidelines refer to Table 1 and Table 2 in section “Dosage/Administration”.

Weight loss and anorexia

Selinexor can cause weight loss and anorexia. Patients should have their body weight, nutritional status and volume checked at baseline, during treatment, and as clinically indicated. Monitoring should be more frequent during the first two months of treatment. Patients experiencing new or worsening decreased appetite and weight may require dose modification, appetite stimulants, and nutritional consultations. For dose modification guidelines refer to Table 1 and Table 2 in section “Dosage/Administration”.

Confusional state and dizziness

Selinexor can cause confusional state and dizziness. Patients should be instructed to avoid situations where dizziness or confusional state may be a problem and to not take other medicinal products that

may cause dizziness or confusional state without adequate medical advice. Patients should be advised not to drive or operate heavy machinery until symptoms resolve (see section “Effects on ability to drive and use machines”).

Hyponatraemia

Selinexor can cause hyponatraemia. Patients should have their sodium levels checked at baseline, during treatment, and as clinically indicated. Monitoring should be more frequent during the first two months of treatment. Correct sodium levels for concurrent hyperglycaemia (serum glucose >150 mg/dL) and high serum paraprotein levels. Hyponatraemia should be treated as per medical guidelines (intravenous sodium chloride solution and/or salt tablets), including dietary review. Patients may require selinexor dose interruption and/or modification. For dose modification guidelines refer to Table 1 and Table 2 in section “Dosage/Administration”.

Cataract

Selinexor can cause new onset or exacerbation of cataract. Grade 3 or 4 and serious cataracts were observed in the clinical studies (see section “Undesirable effects”). Ophthalmologic evaluation may be performed as clinically indicated. Cataract should be treated as per medical guidelines, including surgery if warranted.

Tumour lysis syndrome

Tumour lysis syndrome (TLS) has been reported in patients receiving therapy with selinexor. Patients at a high risk for TLS should be monitored closely. Treat TLS promptly in accordance with institutional guidelines.

Acute cerebellar syndrome

Acute cerebellar syndrome (ACS) was not reported in patients with multiple myeloma, however 3 reversible cases of ACS have been reported in patients with cerebellar abnormalities and other types of cancer (pancreatic cancer and acute myeloid leukaemia) receiving therapy with selinexor.

Women of childbearing potential/contraception in males and females

Women of childbearing potential should be advised to avoid becoming pregnant or abstain from sexual intercourse while being treated with selinexor and for at least 1 week following the last dose of selinexor.

Women of childbearing potential and male patients of reproductive potential should be advised to use effective contraceptive measures or abstain from sexual activity to prevent pregnancy during treatment with selinexor and for at least 1 week following the last dose of selinexor (see section “Pregnancy/Lactation, Fertility”).

Excipients

This medicinal product contains less than 1 mmol sodium (23 mg) per 20 mg tablet, that is to say essentially 'sodium-free'.

Interactions

Pharmacokinetic interactions

Effect of other agents on the pharmacokinetics of selinexor

Concomitant use of strong CYP3A4 inducers might lead to lower exposure of selinexor.

No clinically significant differences in selinexor pharmacokinetics were observed when co-administered with a strong CYP3A4 inhibitor, clarithromycin (500 mg PO twice daily for 7 days).

No clinically significant differences in selinexor pharmacokinetics were observed when co-administered with up to 1000 mg daily dose of paracetamol.

In vitro Studies

CYP Enzymes: Selinexor does not inhibit CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19, or CYP3A4/5. Selinexor is not a CYP3A4, CYP1A2, or CYP2B6 inducer.

Non-CYP Enzyme Systems: Selinexor is a substrate of UGTs and GSTs.

Transporter Systems: Selinexor inhibits OATP1B3 but does not inhibit other solute carrier (SLC) transporters. Selinexor is not a substrate of P-gp, BCRP, OATP1B1, OATP1B3, OAT1, OAT3, OCT1, OCT2, MATE1, or MATE2-K.

Pregnancy, lactation

Women of childbearing age/contraception in men and women

Women of childbearing potential should be advised to avoid becoming pregnant or abstain from sexual intercourse while being treated with selinexor and for at least 1 week following the last dose of selinexor. A pregnancy test is recommended for women of childbearing potential prior to initiating selinexor treatment.

Women of childbearing potential and male patients of reproductive potential should be advised to use effective contraceptive measures or abstain from sexual activity to prevent pregnancy during treatment with selinexor and for at least 1 week following the last dose of selinexor.

Pregnancy

There are no data from the use of selinexor in pregnant women. Studies in animals have shown selinexor can cause foetal harm (see section “Preclinical Data”). Selinexor is not recommended during pregnancy and in women of childbearing potential not using contraception.

If the patient becomes pregnant while taking selinexor, selinexor should be immediately discontinued, and the patient should be apprised of the potential hazard to the foetus.

Lactation

It is unknown whether selinexor or its metabolites are excreted in human milk. A risk to breast-fed children cannot be excluded. Breast-feeding should be discontinued during treatment with selinexor and for 1 week after the last dose.

Fertility

Based on findings in animals, selinexor may impair fertility in females and males (see section “Preclinical Data”).

Effects on ability to drive and use machines.

NEXPOVIO has an influence on the ability to drive and use machines.

Selinexor can cause fatigue, confusional state and dizziness. Patients should be instructed to avoid situations where dizziness or confusional state may be a problem and to not take other medicinal products that may cause dizziness or confusional state without adequate medical advice. Patients should be advised not to drive or operate machines if they experience any of these symptoms.

Undesirable effects

Summary of the safety profile

The safety of selinexor has been evaluated in 409 patients with multiple myeloma, including 214 patients in the STORM Study (which investigated selinexor in combination with dexamethasone) and 195 patients in the BOSTON Study (which investigated selinexor in combination with bortezomib and dexamethasone).

The most frequent adverse reactions ($\geq 30\%$) were thrombocytopenia (63%), nausea (60%), decreased appetite (44%), anaemia (34%), weight decrease (33%), vomiting (29%), and diarrhoea (27%).

The most commonly reported serious adverse reactions ($\geq 10\%$) were thrombocytopenia (48%), anaemia (20%), fatigue (15%), neutropenia (14%), hyponatremia (12%).

The safety of selinexor has been evaluated in 2883 patients in clinical trials in combination with other treatments for both haematologic malignancies and solid tumours, and a consistent safety profile was observed.

List of adverse reactions

The adverse reactions are arranged according to MedDRA system organ classes and the conventional frequencies as follows:

"very common" ($\geq 1/10$)

"common" ($\geq 1/100$, $< 1/10$),

"uncommon" ($\geq 1/1,000$, $< 1/100$)

"rare" ($\geq 1/10,000$, $< 1/1,000$)

"very rare" ($< 1/10,000$)

"not known" (frequency cannot be estimated from the available data)

Adverse reactions reported in patients with multiple myeloma in clinical trials with selinexor are summarised in Table 3.

Table 3: Adverse drug reactions (ADRs) observed in patients treated with selinexor

System organ class / preferred terms	All adverse drug reactions / frequency
Infections and infestations	<p>Common: Upper respiratory tract infection, Pneumonia, Lower respiratory tract infection, Lung infection, Sepsis</p> <p>Uncommon: Nasopharyngitis, Bacteraemia, Cellulitis, Fungal infection, Gastroenteritis, Oral candidiasis, Sinusitis, Urinary tract infection</p>
Blood and lymphatic system disorders	<p>Very Common: Thrombocytopenia (63%), anaemia (34%), neutropenia (23%), leukopenia (16%)</p> <p>Common: Lymphopenia</p>
Endocrine disorders	<p>Uncommon: Hypothyroidism</p>
Metabolism and nutrition disorders	<p>Very Common: Weight decreased (33%), decreased appetite (44%), hyponatraemia (20%)</p> <p>Common: Dehydration, Abnormal potassium level,</p>

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	<p>Hypomagnesaemia, Hyperglycaemia, Hypophosphataemia, Hypercreatininaemia, Hypocalcaemia, Hyperamylasaemia</p> <p>Uncommon: Hyperlipasaemia, Hyperuricaemia, Hypoalbuminaemia, Tumour lysis syndrome</p>
Psychiatric disorders	<p>Common: Confusional state, Insomnia, Anxiety, Depression, Agitation</p> <p>Uncommon: Irritability, Hallucination, Mania, Mental status changes, Personality change</p>
Nervous system disorders	<p>Common: Dysgeusia, Dizziness, Headache, Cognitive disorder, Syncope, Memory impairment, Ageusia</p> <p>Uncommon: Amnesia, Disturbance in attention, Encephalopathy, Paraesthesia, Somnolence, Balance disorder, Polyneuropathy</p>
Eye disorders	<p>Common: Cataract, Vision blurred, Visual impairment</p> <p>Uncommon: Dry eye, Photophobia, Glaucoma</p>
Ear and labyrinth disorders	<p>Uncommon: Vertigo</p>
Cardiac disorders	<p>Common: Tachycardia</p>
Vascular disorders	<p>Common: Hypotension</p> <p>Uncommon: Hypertension</p>
Respiratory, thoracic and mediastinal disorders	<p>Common: Dyspnoea, Epistaxis, Cough, Hiccups</p> <p>Uncommon: Nasal congestion, Pleural effusion, Pneumonitis</p>
Gastrointestinal disorders	<p>Very Common: Nausea (60%), vomiting (29%), Diarrhoea (27%)</p>

Product information for human medicinal products

	<p>Common: Constipation, Abdominal pain, Dyspepsia, Dry mouth, Anal incontinence, Flatulence</p> <p>Uncommon: Gastro-oesophageal reflux disease, Abdominal distension, Eructation, Salivary hypersecretion</p>
Skin and subcutaneous tissue disorders	<p>Common: Alopecia, Night sweats</p> <p>Uncommon: Hyperhidrosis, Pruritus, Rash, Skin fissures</p>
Musculoskeletal and connective tissue disorders	<p>Common: Muscle spasms, Muscular weakness, Bone pain</p>
Renal and urinary disorders	<p>Common: Acute kidney injury</p> <p>Uncommon: Urinary incontinence</p>
General disorders and administration site conditions	<p>Very Common: Fatigue (48%), asthenia (15%)</p> <p>Common: Pyrexia, Malaise, Chills, Gait disturbance</p> <p>Uncommon: Influenza-like illness, Oedema peripheral</p>
Investigations	<p>Common: Alanine aminotransferase increased, Aspartate aminotransferase increased, Blood alkaline phosphatase increased</p> <p>Uncommon: C-reactive protein increased, Haematocrit decreased</p>
Injury, poisoning and procedural complications	<p>Uncommon: Contusion, Fall, Subdural haematoma</p>

Description of specific adverse reactions and additional information

Infections

Infection was the most common non-haematological toxicity.

In the BOSTON Study in patients who received SVd, infections were reported in 70% of patients and 28% of patients had Grade 3 or 4 infections. Serious infections were reported in 28% of patients with fatal infections occurring in 4% of treated patients. Upper respiratory tract infection and pneumonia were the most commonly reported infections in 21% and 15% of patients, respectively. Infection led to dose discontinuation in 1% of patients, treatment interruption in 48% patients, and a dose reduction in 10% of patients.

In the STORM Study in patients who received Sd, infections were reported in 53% of patients. Of these, 22% were Grade 3 or 4. Upper respiratory tract infection and pneumonia were the most commonly reported infections (in 15% and 13% of patients, respectively) with 25% of reported infections being serious and fatal infections occurring in 3% of treated patients. Infection led to dose discontinuation in 7% of patients, treatment interruption in 19% patients, and a dose reduction in 1% of patients.

Thrombocytopenia

In the BOSTON study in patients who received SVd, thrombocytopenia occurred in 62% of patients and 41% of patients had Grade 3 or 4 thrombocytopenia. Thrombocytopenia was serious in 2% of patients. Of the 41% patients with Grade 3 or 4 thrombocytopenia, Grade 3 or higher concurrent (defined as ± 5 days) bleeding events were reported in 5% of patients. Fatal haemorrhage occurred in 2% of patients with thrombocytopenia. Thrombocytopenia led to dose discontinuation in 2% of patients, treatment interruption in 35% of patients, and a dose reduction in 33% of patients.

In the STORM Study in patients who received Sd, thrombocytopenia occurred in 75% of patients and 65% of these ADRs were Grade 3 or 4. Thrombocytopenia was serious in 5% of patients. Of the 65% patients with Grade 3 or 4 thrombocytopenia, serious/Grade 3 or higher concurrent (defined as ± 5 days) bleeding events were reported in 5% of patients. Thrombocytopenia led to dose discontinuation in 3% of patients, treatment interruption in 22% of patients, and a dose reduction in 32% of patients. Thrombocytopenia can be managed with dose modifications (see section "Dosage/Administration"), supportive care and platelet transfusions. Patients should be monitored for signs and symptoms of bleeding and evaluated promptly (see section "Warnings and Precautions").

Neutropenia

In the BOSTON study, in patients who received SVd, neutropenia occurred in 16% of patients and 10% of patients had Grade 3 or 4 events of neutropenia. Neutropenia was serious in 1% of patients. None of the patients had a dose discontinuation due to neutropenia, and neutropenia led to treatment interruption in 9% of patients, and a dose reduction in 5% of patients.

Febrile neutropenia, reported as serious, occurred in one patient (<1%) who received SVd and was Grade 4. Febrile neutropenia led to treatment interruption and dose reduction; no dose discontinuation occurred due to febrile neutropenia. Of the 19 patients with Grade 3 or higher

neutropenia, serious/Grade 3 or higher concurrent (defined as ± 5 days) infections were reported in 3 (16%) patients. Concurrent Grade 3 or higher infections included lower respiratory tract infection, bronchitis and ear infection (1 patient each).

In the STORM study in patients who received Sd, neutropenia occurred in 36% of patients and 25% of these were Grade 3 or 4. Neutropenia was serious in 1% of patients. None of the patients had a dose discontinuation due to neutropenia, and neutropenia led to treatment interruption in 2% of patients, and a dose reduction in 6% of patients.

Febrile neutropenia occurred in 3% of patients who received Sd; all were Grade 3 or 4. Febrile neutropenia was reported to be serious in 2% of patients and led to a dose discontinuation, treatment interruption, or a dose reduction in less than 1% of patients (each). Of the 53 patients with Grade 3 or higher neutropenia, serious/Grade 3 or higher concurrent infections (defined as ± 5 days) were reported in 6 (11%) patients. The most commonly reported Grade 3 or higher concurrent infections included urinary tract infection (3 patients) and sepsis (2 patients).

Anaemia

In the BOSTON study, in patients who received SVd, anaemia occurred in 37% of patients and 16% of patients had Grade 3 anaemia; no patients had Grade 4 or 5 anaemia. Anaemia was serious in 3% of patients. Anaemia led to dose discontinuation in 1% of patients, treatment interruption in 6% of patients, and a dose reduction in 3% of patients.

In the STORM study in patients who received Sd, anaemia occurred in 61% of patients and 44% of these were Grade 3 or 4. Anaemia was serious in 3% of patients. Anaemia led to dose discontinuation in <1% of patients, treatment interruption in 4% of patients, and a dose reduction in 1% of patients.

Anaemia can be managed with dose modifications (see section “Dosage/Administration”) and with blood transfusions and/or erythropoietin administration as per medical guidelines. For dose modification guidelines refer to Table 2 of section “Dosage/Administration”.

Gastrointestinal toxicity

In the BOSTON study, in patients who received SVd, nausea occurred in 50% of patients and 8% of patients had Grade 3 or 4 nausea. Nausea was serious in 2% of patients. When anti-nausea treatment was administered, the median duration of nausea improved by 10 days. Nausea led to dose discontinuation in 3% of patients, treatment interruption in 7% of patients, and a dose reduction in 7% of patients.

Vomiting occurred in 21% of patients who received SVd, and 4% of patients had Grade 3 vomiting. No patients had Grade 4 vomiting. Vomiting was serious in 4% of patients. Vomiting led to dose discontinuation in 2% of patients, treatment interruption in 3% of patients, and a dose reduction in 3% of patients.

Diarrhoea occurred in 33% of patients who received SVd and 7% of patients had Grade 3 or 4 diarrhoea. Diarrhoea was serious in 4% of patients. Diarrhoea led to dose discontinuation in 1% of patients, treatment interruption in 8% of patients, and a dose reduction in 2% of patients.

In the STORM study in patients who received Sd, nausea/vomiting occurred in 79% of patients and 10% of these cases were Grade 3 or 4 and were serious in 3% of patients. When anti-nausea treatment was administered, the median duration of nausea or vomiting improved by 3 days. Nausea/vomiting led to dose discontinuation in 5% of patients, treatment interruption in 8% of patients, and a dose reduction in 5% of patients.

Diarrhoea occurred in 47% of patients who received Sd and 7% were Grade 3 or 4 and diarrhoea was serious in 2% of patients. Diarrhoea led to dose discontinuation in 1% of patients, treatment interruption in 2% of patients, and a dose reduction in 1% of patients.

Hyponatraemia

In the BOSTON study, in patients who received SVd, hyponatraemia occurred in 8% of patients and 5% of patients had Grade 3 or 4 hyponatraemia. Hyponatraemia was serious in <1% of patients. Most cases of hyponatraemia were not associated with any symptoms. There were no reports of concurrent seizures (defined as ± 5 days). Hyponatraemia did not lead to any dose discontinuations, and it led to treatment interruption in <1% of patients, and a dose reduction in 1% of patients.

In the STORM study in patients who received Sd, hyponatraemia occurred in 40% of patients and 24% were Grade 3 or 4. Hyponatraemia was serious in 3% of patients. Most cases of hyponatraemia were not associated with any symptoms. There were no reports of concurrent seizures (defined as ± 5 days). Hyponatraemia did not lead to any dose discontinuations, and it led to treatment interruption in 6% of patients, and a dose reduction in 1% of patients.

Cataract

In the BOSTON study in patients receiving SVd, the incidence of new onset or worsening cataracts requiring clinical intervention was reported in 24% of patients. The median time to new onset of cataract was 233 days. The median time for worsening of cataract in patients presenting with cataract at the start of selinexor therapy was 261 days (SVd). Cataract did not lead to treatment discontinuation, it led to treatment interruption in 4% of patients and a dose reduction in 3% of patients. Grade 3 or 4 cataract was observed in 11.3% of patients in the SVd arm and 2% of patients in the Vd arm, and serious cataract was observed in 9 patients in the SVd arm of the BOSTON study. Cataract should be treated as per medical guidelines, including surgery if warranted (see sections "Warnings and Precautions" and "Dosage/Administration").

Tumour lysis syndrome

Tumour lysis syndrome (TLS) occurred in one (<1%) patient (who received selinexor); this was considered Grade 3 and serious. Patients at a high risk for TLS should be monitored closely. Treat TLS promptly in accordance with institutional guidelines (see section “Warnings and Precautions”).

Cardiac electrophysiology

The effect of multiple doses of selinexor up to 175 mg twice weekly on the QTc interval was evaluated in patients with heavily pre-treated haematologic malignancies. Selinexor had no large effect (i.e. no greater than 20 ms) on QTc interval at the therapeutic dose level. In the BOSTON study, 8 patients from the SVd arm (8%) and 1 patient from the Vd arm (2%) had QTc increase from baseline >60 during the study. Among these patients, 2 had a QTcF increase to >500 ms in the SVd arm. No events of torsade de pointes or other ventricular arrhythmia were reported.

Specific populations

Elderly population

In the STORM study, among patients with multiple myeloma who received Sd, 47% were 65 years of age and over, while 11% were 75 years of age and over. When comparing patients 75 years of age and older to younger patients, older patients had a higher incidence of discontinuation due to an adverse reaction (52% vs 25%), higher incidence of serious adverse reactions (74% vs 59%), and higher incidence of fatal adverse reactions (22% vs 8%).

Reporting suspected adverse reactions after authorisation of the medicinal product is very important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions online via the EIVIS portal (Electronic Vigilance System). You can obtain information about this at www.swissmedic.ch.

Overdose

In general, overdoses have been associated with similar side effects to those reported for standard dosing and have generally been reversible within 1 week.

Signs and symptoms

Potential acute symptoms include nausea, vomiting, diarrhoea, dehydration and confusion. Potential signs include low sodium levels, elevated liver enzymes, and low blood counts. Patients should be monitored closely and provided supportive care as appropriate. No fatalities due to overdose have been reported to date.

Treatment

In the event of an overdose, monitor the patient for any adverse reactions and appropriate symptomatic treatment should be provided immediately.

Properties/Effects

ATC code

Pharmacotherapeutic group: Antineoplastic agents, other antineoplastic agents, ATC code: L01XX66.

Mechanism of action

Selinexor is a reversible covalent selective inhibitor of nuclear export (SINE) compound that specifically blocks exportin 1 (XPO1). XPO1 is the major mediator of the nuclear export of many cargo proteins including tumour suppressor proteins (TSPs), growth regulators and mRNAs of growth promoting (oncogenic) proteins. XPO1 inhibition by selinexor leads to marked accumulation of TSPs in the nucleus, cell cycle arrest, reductions in several oncoproteins such as c-Myc and cyclin D1, and apoptosis of cancer cells. The combination of selinexor and dexamethasone demonstrated synergistic cytotoxic effects in multiple myeloma in vitro and increased anti-tumour activity in murine xenograft multiple myeloma models in vivo, including those resistant to proteasome inhibitors.

Pharmacodynamic

Clinical efficacy

The efficacy of NEXPOVIO in combination with dexamethasone was evaluated in study KCP-330-012 (STORM), a phase 2, multi-centre, single-arm, open-label, study, in which patients with relapsed and/or refractory multiple myeloma (RRMM) took part. STORM Part 2 required patients to have measurable disease per IMWG criteria, have previously received three or more antimyeloma treatment regimens including an alkylating agent, glucocorticoids, bortezomib, carfilzomib, lenalidomide, pomalidomide, and an anti-CD38 monoclonal antibody; and whose myeloma was documented to be refractory to glucocorticoids, a proteasome inhibitor, an immunomodulatory agent, an anti-CD38 monoclonal antibody, and to the last line of therapy. Patients had to have an ECOG performance status score ≤ 2 , adequate hepatic, renal and haematopoietic function. Systemic light chain amyloidosis, active central nervous system myeloma, peripheral neuropathy of Grade 3 or higher, or painful neuropathy of Grade 2 or higher were exclusion criteria.

Patients were treated with 80 mg selinexor in combination with 20 mg dexamethasone on Days 1 and 3 of every week. Treatment continued until disease progression, death or unacceptable toxicity. Among patients enrolled in STORM Part 2 (n=123), eighty-three (83) patients had RRMM that was refractory to two proteasome inhibitors (bortezomib, carfilzomib), two immunomodulators (lenalidomide, pomalidomide) and an anti-CD38 monoclonal antibody (daratumumab). The median duration of selinexor treatment in these 83 patients was 9 weeks (range: 1 to 61 weeks). The median total dose of selinexor received was 880 mg (range 160 to 6,220 mg), with a median dose of 105 mg (range: 22 to 180 mg) received per week.

Among the 83 patients whose disease was penta-refractory (refractory to bortezomib (B), carfilzomib (C), lenalidomide (L), pomalidomide (P), and daratumumab (D)), the majority of patients were male (61%) and the median age was 65 years (range 40-86). The median duration from diagnosis was 7 years and patients had a median of 8 prior therapy regimens (range 4-18). The majority of patients (81%) had previous stem cell transplant including 28% who had more than 2 previous transplants, and 2 patients had previous CAR-T Cell Therapy. Most patients had an ECOG PS of 0 or 1 (89%), a Revised Integrated Staging System stage of II (68%) and were considered to have a 'high-risk' disease per their multiple myeloma's cytogenetic markers (57%).

The primary efficacy endpoint was overall response rate (ORR) as assessed by an Independent Review Committee based on the IMWG uniform response criteria for multiple myeloma. Responses were assessed monthly and as per IMWG guidelines. Table 8 provides an overview of the efficacy results.

Table 7: Efficacy results: assessed by Independent Review Committee (STORM, adult patients who have received at least 4 prior therapies with multiple myeloma refractory to at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody and who were treated with twice weekly 80 mg selinexor and 20 mg dexamethasone)

Efficacy endpoint	NEXPOVIO + dexamethasone n=83
Overall response rate (ORR), n (%) (includes sCR + VGPR + PR) ¹	21 (25.3)
95% confidence interval	16.4, 36
sCR, MRD negative, n (%)	1 (1.2)
CR, n (%)	0 (0)
VGPR, n (%)	4 (4.8)
PR, n (%)	16 (19.3)
Minimal response (MR), n (%)	10 (12.0)
Stable disease (SD), n (%)	32 (38.6)

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Progressive disease (PD) /not evaluable (NE), n (%)	20 (24.1)
Median time to first response (weeks) (range: 1 to 10 weeks)	3.9
Median duration of response (DOR) months (95% confidence interval)	3.8 (2.3, 10.8)

¹sCR= stringent complete response, CR= complete response, VGPR= very good partial response, PR= partial response

These efficacy results correspond to an analysis based on the 26 July 2019 data cut off.

The OS-Analysis was performed at the data cut off date of September 2019. The observed median overall survival (OS) in the penta-refractory population in the STORM study (N=83) was 8 months. The number of death events was 54..

Paediatrics

The efficacy of NEXPOVIO in children and adolescents has not been established.

Pharmacokinetics

Absorption

Following oral administration of selinexor peak plasma concentration, C_{max} is reached within 4 hours. Concomitant administration of a high fat meal (800-1'000 calories with approximately 50% of total caloric content of the meal from fat) did not have a clinically significant effect on the pharmacokinetics of selinexor.

Distribution

Selinexor is 95.0% bound to human plasma proteins. In a population pharmacokinetic (PK) analysis, the apparent volume of distribution (Vd/F) of selinexor was 133 l in cancer patients.

Metabolism

Selinexor is metabolised by CYP3A4, multiple UDP-glucuronosyltransferases (UGTs) and glutathione S-transferases (GSTs).

Elimination

Following a single dose of 80 mg selinexor the mean half-life ($t_{1/2}$) is 6 to 8 hours. In a population PK analysis, the apparent total clearance (CL/F) of selinexor was 18.6 l/h in cancer patients.

Kinetics in specific patient groups

Age (18 to 94 years of age), sex, or race had no clinically significant effect on the pharmacokinetics of selinexor.

In the population PK dataset, age and race were not identified as a significant covariate, gender was identified as a significant covariate.

Hepatic impairment

Population PK analysis indicated that mild hepatic impairment (bilirubin $>1-1.5 \times \text{ULN}$ or $\text{AST} > \text{ULN}$, but bilirubin $\leq \text{ULN}$, $n=119$) had no clinically significant effect on the PK of selinexor. Similar finding was observed in a small number of patients with moderate (bilirubin $>1.5-3 \times \text{ULN}$; any AST, $n=10$) and serious hepatic impairment (bilirubin $>3 \times \text{ULN}$; any AST, $n=3$).

Renal impairment

The degree of renal impairment was determined by creatinine clearance as estimated by the Cockcroft-Gault equation. Results from population PK analyses of patients with normal ($n=283$, $\text{CL}_{\text{cr}}: \geq 90 \text{ ml/min}$), mild ($n=309$, $\text{CL}_{\text{cr}}: 60 \text{ to } 89 \text{ ml/min}$), moderate ($n=185$, $\text{CL}_{\text{cr}}: 30 \text{ to } 59 \text{ ml/min}$) or serious ($n=13$, $\text{CL}_{\text{cr}}: 15 \text{ to } 29 \text{ ml/min}$) renal dysfunction indicated that creatinine clearance had no impact on the PK of NEXPOVIO. Therefore, mild, moderate, or serious renal impairment is not expected to alter selinexor PK, and no adjustments in the dose of selinexor are required in patients with renal dysfunction.

Preclinical data

Repeated dose toxicity

Findings in the repeat dose 13-week rat study were decrements in body weight gain and food consumption, and haematopoietic/lymphoid hypoplasia, and male/female reproductive organ effects. In the 13-week monkey study, the treatment-related effects observed included body weight loss, gastrointestinal effects, and lymphoid/haematologic depletion. Gastrointestinal toxicities, including anorexia, decrements in body weight gain and reduced food consumption were noted to be CNS-mediated. No safety margin for these toxicities could be established.

Genotoxicity

Selinexor was not mutagenic in a bacterial reverse mutation assay. Selinexor was not clastogenic in either the in vitro cytogenetic assay in human lymphocytes or in the in vivo rat micronucleus assay.

Carcinogenicity

Carcinogenicity studies have not been conducted with selinexor.

Reproductive toxicity

Fertility studies in animals have not been conducted with selinexor. In repeat-dose oral toxicity studies, selinexor was administered for up to 13 weeks in rats and monkeys. Reduced sperm, spermatids, and germ cells in epididymides and testes were observed in rats, decreased ovarian follicles were also observed in rats, and single cell necrosis of testes was observed in monkeys. These findings were observed at systemic exposures approximately 0.11, 0.28, and 0.53 times, respectively, the exposure (AUC_{last}) in humans at the recommended human dose of 80 mg. Developmental effects were seen with daily exposure in pregnant rats at systemic exposures below the exposure (AUC_{last}) in humans at the recommended human dose of 80 mg.

Other Toxicities

A guinea pig sensitisation assay showed that selinexor at 25% induced a mild Grade II dermal contact hypersensitivity response at 24 and 48 hours.

Other information

Incompatibilities

Not applicable.

Shelf life

Do not use this medicine after the expiry date ("EXP") stated on the pack.

Special precautions for storage

Store in the original packaging and not above 30°C.

Keep out of the reach of children.

Instructions for handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Authorisation number

69230 (Swissmedic)

Packs

Each outer carton contains four child-resistant inner packs. Each inner pack contains one plastic blister with 2, 3, 4, 5, or 8 tablets, providing a total of 8, 12, 16, 20, or 32 tablets.

NEXPOVIO, 20 mg, 8 Film-coated Tablets, (A)

NEXPOVIO, 20 mg, 12 Film-coated Tablets, (A)

NEXPOVIO, 20 mg, 16 Film-coated Tablets, (A)

NEXPOVIO, 20 mg, 20 Film-coated Tablets, (A)

NEXPOVIO, 20 mg, 32 Film-coated Tablets, (A)

Marketing authorisation holder

Stemline Therapeutics Switzerland GmbH, Zug

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