swissmedic

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Swissmedic, Swiss Agency for Therapeutic Products

Swiss Public Assessment Report

Voraxaze

International non-proprietary name:	glucarpidase
Pharmaceutical form:	powder for solution for injection
Dosage strength(s):	1000 units
Route(s) of administration:	intravenous
Marketing authorisation holder:	Curatis AG
Marketing authorisation no.:	70288
Decision and decision date:	approved on 04 September 2026

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

ADA	Anti-drug antibody
ADME	Absorption, distribution, metabolism, elimination
AE	Adverse event
ALT	Alanine aminotransferase
API	Active pharmaceutical ingredient
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical Classification System
AUC	Area under the plasma concentration-time curve
$AUC_{0\text{-}24h}$	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
EMA	European Medicines Agency
ERA	Environmental risk assessment
FDA	Food and Drug Administration (USA)
GI	Gastrointestinal
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
MAA	Marketing authorisation application
MAH	Marketing authorisation holder
Max	Maximum
Min	Minimum
MRHD	Maximum recommended human dose
N/A	Not applicable
NO(A)EL	No observed (adverse) effect level
PBPK	Physiology-based pharmacokinetics
PD	Pharmacodynamics
PIP	Paediatric investigation plan (EMA)
PK	Pharmacokinetics
PopPK	Population pharmacokinetics
PSP	Pediatric study plan (US FDA)
RMP	Risk management plan
SAE	Serious adverse event
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) and information regarding procedure

New active substance status
The applicant requested new active substance status for glucarpidase 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 21 May 2026.

2.2 Indication and dosage

2.2.1 Requested indication

Voraxaze is indicated to reduce toxic plasma methotrexate concentration in adults and children (aged 28 days and older) with delayed methotrexate elimination or at risk of methotrexate toxicity.

2.2.2 Approved indication

Voraxaze is indicated to reduce toxic plasma methotrexate concentrations in adults and children (aged 28 days and older) with delayed methotrexate elimination due to renal dysfunction (see "Dosage/Administration", "Clinical efficacy").

2.2.3 Requested dosage

A single dose of 50 Units per kilogram (kg) of body weight is given as an i.v. bolus injection over 5 min.

2.2.4 Approved dosage

(see appendix)

2.3 Regulatory history (milestones)

Application	23 December 2025
Formal control completed	7 January 2026
Preliminary decision	6 May 2026
Response to preliminary decision	28 June 2026
Final decision	4 September 2026
Decision	approval

3 Medical context

Acute methotrexate (MTX) toxicity is a rare and life-threatening condition. Toxic plasma MTX concentrations are associated with severe tissue damage including mucositis, rash, fever, myelosuppression, renal and hepatic dysfunction, and may progress to multiorgan failure. Reported mortality rates remain high (e.g., approximately 28%).[1]
Although several MTX thresholds (e.g. ≥5 to 10 µmol/L at 24 hours, ≥1 µmol/L at 48 hours, and ≥0.1 µmol/L at 72 hours) have been associated with an increased risk of toxicity, no universally accepted threshold for MTX intoxication exists.[2]

There is currently no approved treatment in Switzerland to reduce toxic systemic MTX concentrations. Thus, there is an unmet medical need.

4 Quality aspects

4.1 Drug substance

INN: Glucarpidase

Molecular mass:
Glucarpidase is a zinc-dependent exopeptidase enzyme with co-catalytic zinc ion centres and a conserved aminopeptidase fold. It has a subunit molecular mass of 41,440 daltons and a dimeric molecular weight of 83 kDa.

Molecular structure:
The molecular formula for glucarpidase monomer (protein only) is $C_{1950}H_{3157}N_{543}O_{599}S_7$.
Reference WHO 2005 listing online:
https://www.who.int/publications/m/item/inn-rl-54

Manufacture:
The Applicant has provided a list of manufacturing and testing sites for this recombinant protein. The drug substance is manufactured at Eurogentec in Belgium, and it starts with fermentation in *E. coli.*

Specification:
The drug substance specifications are sufficiently described in the MA dossier.

Stability:
The proposed long-term storage condition for the drug substance is 6 months at -20 ± 5°C.

4.2 Drug product

Description and composition:
Voraxaze is supplied as a sterile, freeze-dried preparation. Each vial contains a nominal 1000 Units of glucarpidase, intended for injection after reconstitution with 1 mL of sterile normal saline.

The normal saline is not included in the pack.

[1] Ajmani S et al. Int J Rheum Dis. 2017 Jul;20(7):846-851. doi: 10.1111/1756-185X.13004. Epub 2017 Mar 5.
[2] Wideman B. et al. Understanding and Managing Methotrexate Nephrotoxicity. The Oncologist. 2006.

Voraxaze is supplied in a 1 vial pack size.

Table 1 Composition of each vial of Voraxaze

Ingredient	Function	Reference	Quantity
Glucarpidase	Active	In-house	1000 Units
Lactose monohydrate	Bulking agent	Ph. Eur. / NF	10 mg (1%)
Tris-HCl pH 7.7	pH Control buffer	Tris(hydroxymethyl)aminomethane Ph. Eur. / USP	Carried over as a constituent of the bulk purified material
Zn^{2+}	Zinc Buffer (Zinc is needed for enzyme activity)	Zinc Acetate dihydrate (Ph. Eur. / USP)	0.01 mM

Pharmaceutical development:
The pharmaceutical development has been sufficiently described in the dossier.

Manufacture:
The Applicant has provided a list of finished product manufacturing and testing sites. Aseptic production of the finished product is undertaken at Bora Pharmaceuticals in Baltimore, USA.

Specification:
The drug product specifications are sufficiently described in the MA dossier.

Container Closure System:
A borosilicate glass vial is used. The container complies with the requirement for the neutral glass, hydrolytic Type I as described in current European Pharmacopoeia (Ph. Eur.), Section 3.2.1 Glass Containers for Pharmaceutical Use.

Stability:
Based on the studies conducted to date, as well as supportive data from full-scale development lots, a shelf life of 60 months when stored at 2 - 8°C is supported.

4.3 Quality conclusions

Satisfactory and consistent quality of the drug substance and drug product has been demonstrated.

5 Nonclinical aspects

For the review of the MAA for Voraxaze, the Division Nonclinical Assessment conducted an abridged evaluation, which was based on the CHMP assessment report of the EMA dated 11 November 2021 (EMA/CHMP/422969/2021) provided by the applicant.

Overall, the submitted nonclinical documentation is considered appropriate to support the approval of Voraxaze in the proposed indication. The pharmaco-toxicological profile has been sufficiently characterised. All nonclinical data that are relevant for safety are adequately mentioned in the Information for healthcare professionals.

6 Clinical aspects

6.1 Clinical pharmacology

Swissmedic has not assessed the primary data relating to clinical pharmacology aspects submitted with this application and relies on the assessments of the foreign authorities, the EMA (report dated 11 November 2021) and FDA (report dated 12 January 2012).

For further information regarding clinical pharmacology aspects, please refer to the attached Information for healthcare professionals.

6.2 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 assessments of the EMA and FDA. The clinical evaluation focused on data submitted regarding the specific indication wording.

Four open-label, single-arm studies were submitted to evaluate the efficacy and safety of glucarpidase. In accordance with the eligibility criteria, these studies investigated patients with delayed methotrexate elimination due to impaired renal function. To adequately reflect the studied population, this aspect was included in the indication.

For further information regarding clinical aspects, please refer to the attached Information for healthcare professionals.

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 Voraxaze 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-pro.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.

Voraxaze, powder for solution for injection

Composition

Active substances

Glucarpidase*
* Produced from *Escherichia coli* cells by recombinant DNA technology.

Excipients

Lactose monohydrate, trometamol, zinc acetate dihydrate

Pharmaceutical form and active substance quantity per unit

White to off-white powder for solution for injection.
After reconstitution with 1 mL of sterile 0.9% sodium chloride solution, each vial contains a nominal 1000 units of glucarpidase.

Indications/Uses

Voraxaze is indicated to reduce toxic plasma methotrexate concentrations in adults and children (aged 28 days and older) with delayed methotrexate elimination due to renal dysfunction (see “Dosage/Administration”, “Clinical efficacy”).

Dosage/Administration

Glucarpidase is intended for use under medical supervision.
In order to improve the traceability of biological medicinal products, the trade name and the batch number of the administered product should be clearly recorded.
Recommendations for intervention with glucarpidase are considered when plasma MTX levels are greater than 2 standard deviations of the mean expected MTX excretion curve. Also, administration of glucarpidase should optimally occur within 60 hours from the start of the high-dose MTX infusion because life-threatening toxicities may not be preventable beyond this time point. Clinical data however show that glucarpidase continues to be effective beyond this time window.
For recommendations for intervention with glucarpidase depending on the threshold plasma MTX concentration, refer to local and international treatment protocols and guidelines.

Dosage

The recommended dose is a single dose of 50 units per kilogram (kg) of body weight by bolus intravenous (IV) injection over 5 minutes.
Once the diagnosis of delayed methotrexate (MTX) elimination or risk for MTX toxicity is established, glucarpidase should be administered without delay. For patients with delayed MTX elimination, the optimal time window for administration is within 48–60 hours from the start of the high-dose MTX infusion. Folinic acid, also known as leucovorin, is a competitive substrate of glucarpidase that may compete with MTX for MTX binding sites (see also “Interactions” section). It is therefore recommended that folinic acid should not be administered within the 2 hours before or after glucarpidase administration to minimise potential interactions. Intracellular MTX will continue to inhibit reduction of folate to its active form following glucarpidase administration; thus folinic acid will continue to be needed no earlier than 2 hours post glucarpidase administration in order to replenish the intracellular source of biologically active folate (see “Warnings and precautions” section).

Specific patient populations

Patients with renal impairment

A study of the pharmacokinetics of glucarpidase in the absence of MTX in 4 patients with severe renal impairment (CLcr <30 mL/min) showed that the mean pharmacokinetic parameters were similar to those observed in healthy subjects.
On this basis, no dose adjustment of glucarpidase is recommended for patients with renal impairment.

Children and adolescents

No dose adjustment is required for children and adolescents.

Children aged less than 28 days

No data are available in children aged less than 28 days.

Mode of administration

Reconstitute each vial of Voraxaze 1000 units with 1 mL of sterile 0.9% sodium chloride solution before use. Reconstitution should take place immediately prior to use (do not further dilute). The solution should be administered intravenously by bolus injection over 5 minutes.
After reconstitution with 1 mL of sterile 0.9% sodium chloride solution, each 1 millilitre will contain 1000 units of glucarpidase.
A syringe suitable for withdrawing small volumes should be used to remove the solution from the vial. It may not always be possible to withdraw a full 1 mL from the vial but removal of at least 0.90 mL from the vial will provide an adequate amount of glucarpidase for dosing purposes.
Flush intravenous line before and after administration.

Contraindications

Voraxaze must not be used in patients with known hypersensitivity to any of the components of this medicinal product.

Warnings and precautions

Continuous monitoring

It is important to measure baseline plasma MTX concentrations and renal function and to continue to monitor these throughout high-dose MTX therapy.

A high performance liquid chromatography (HPLC) method is recommended for measuring MTX concentrations following glucarpidase administration. Current immunoassays are unreliable for samples collected following glucarpidase administration due to 2,4-diamino-N10-methylpteroic acid (DAMPA), an inactive metabolite of MTX formed following glucarpidase administration, interfering with the measurement of MTX concentration. This interference results in an overestimation of the MTX concentration. The effect of DAMPA interference will decline gradually over time as DAMPA is eliminated.

DAMPA concentrations in patients treated with glucarpidase fell within a mean half-life of 8.6 hours. In the majority of patients, DAMPA concentrations had fallen to below 1 µmol/L within 48 hours of administration of glucarpidase. In clinical studies, DAMPA concentrations >1 µmol/L have been observed beyond 3 days in a small minority (≤3%) of patients.

In the absence of a more specific HPLC assay, it is recommended that the dose of folinic acid used in a 48-hour period after glucarpidase should be based on the MTX concentration from a sample taken prior to glucarpidase administration. Within 48 hours after glucarpidase administration, MTX concentrations determined by immunoassay cannot be reliably used to monitor for rebound, and confirmatory HPLC data should be considered.

Over 48 hours after glucarpidase administration, immunoassay results will be reliable in the majority of patients and so can be used to adjust the folinic acid dose and monitor patients for rebound. In clinical studies, ~9% of patients with baseline MTX concentration ≥50 µmol/L had DAMPA levels that persisted above 1 µmol/L beyond 4 days.

Routine monitoring of plasma MTX concentrations should be continued in accordance with local guidelines.

Renal impairment

Glucarpidase cannot reverse pre-existing renal damage or renal impairment that occurs as a consequence of MTX administration, but it can remove MTX to reduce the risk of persistent renal toxicity. In addition, other supportive care such as hydration and alkalinisation of the urine should be started at the onset of MTX administration and continued in accordance with local treatment guidelines.

Hypersensitivity reactions
Allergic-type hypersensitivity reactions are possible following administration of glucarpidase (see "Undesirable effects" section).

Interactions

Glucarpidase can reduce folinic acid concentration, which may decrease the effect of folinic acid rescue unless it is dosed as recommended (see "Dosage/Administration" section).
Glucarpidase may also reduce the concentrations of other folate analogues or folate analogue metabolic inhibitors.
The ability of the main metabolite of MTX produced by the action of glucarpidase on MTX (DAMPA) to induce or inhibit CYP450 metabolising isoenzymes has been investigated *in vitro*, which revealed possible enzyme induction with CYP1A2 and CYP2C9. Modest induction would only be expected in a minority of patients who have the highest DAMPA exposure.

Pregnancy, lactation

Pregnancy
There are no data from the use of glucarpidase in pregnant women. Glucarpidase is administered in combination with MTX, which is contraindicated in pregnancy. As use of MTX, a genotoxic and teratogenic agent, is a prerequisite for the use of glucarpidase, this medicinal product is not thought to present an additional risk to patients already receiving MTX. Reproductive studies of glucarpidase in animals were not performed. It is unknown whether glucarpidase causes harmful effects during pregnancy and/or on the foetus/newborn child or whether it can affect reproductive capacity. Glucarpidase should only be given to a pregnant woman if clearly needed.

Lactation
It is unknown whether glucarpidase/its metabolites are excreted in human milk. A risk to newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from glucarpidase therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility
There is no or limited amount of data on the impact of glucarpidase on human fertility. Fertility studies in animals were not performed. It is unknown whether glucarpidase affects fertility.

Effects on ability to drive and use machines

Glucarpidase has no or negligible influence on the ability to drive and use machines.

Undesirable effects

Summary of the safety profile

The most frequent glucarpidase-related undesirable effects were burning sensation (<1%), headache (<1%), paraesthesia (2%), flushing (2%) and feeling hot (<1%).

The undesirable effects listed below are a combination of pooled data from clinical studies (489 patients) and undesirable effects reported from post-marketing experience.
Undesirable effects are arranged according to MedDRA system organ classes and frequency using the following convention: “very common” (≥1/10), “common” (≥1/100, <1/10), “uncommon” (≥1/1000, <1/100), “rare” (≥1/10,000, <1/1000), “very rare” (<1/10,000).

Immune system disorders
Rare: Hypersensitivity
Very rare: Anaphylactic reactions

Nervous system disorders
Uncommon: Burning sensation, headache, paraesthesia
Rare: Hypoaesthesia, somnolence, tremor

Cardiac disorders
Very rare: Tachycardia

Vascular disorders
Uncommon: Flushing
Rare: Hypotension

Respiratory, thoracic and mediastinal disorders
Rare: Pleural effusion, throat tightness

Gastrointestinal disorders
Rare: Abdominal pain upper, diarrhoea, nausea, vomiting

Skin and subcutaneous tissue disorders
Rare: Pruritus, rash
Very rare: Drug eruption, skin reaction

Renal and urinary disorders
Very rare: Crystalluria*

General disorders and administration site conditions

Uncommon: Feeling hot

Rare: Pyrexia, rebound effect

Very rare: Infusion site reaction

*Crystalluria is the preferred term; the adverse reaction refers to DAMPA crystalluria

Description of specific adverse reactions and additional information

As with any intravenous protein product, infusion-related reactions or hypersensitivity reactions are possible.

It is recommended that patients be monitored for signs and symptoms of anaphylaxis and an acute allergic reaction. Medical support must be readily available when glucarpidase is administered.

Immunogenicity

As with all therapeutic proteins, there is potential for immunogenicity. 205 patients who received one (n=176), 2 (n=27) or 3 (n=2) doses of glucarpidase were evaluated for anti-glucarpidase antibodies. Forty-three of these 205 patients (21%) had detectable anti-glucarpidase antibodies following administration, of which 32 received one dose and 11 received 2 or 3 doses of glucarpidase. Antibody titres were determined using a bridging enzyme-linked immunosorbent assay (ELISA) for anti-glucarpidase antibodies. Neutralising antibodies were detected in 22 of the 43 patients who tested positive for anti-glucarpidase binding antibodies.

Children and adolescents

The safety profile in the paediatric population was similar to that in the adult population.

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 new or serious adverse reactions online via the ElViS portal (Electronic Vigilance System). You can obtain information about this at www.swissmedic.ch.

Overdose

The safety profile of the nine patients who received the highest doses of Voraxaze in clinical studies (single dose range of 90.9–188.7 U/kg and/or cumulative dose range of 150.0–201.8 U/kg) was similar to the safety profile of all patients.

In case of overdose, it is recommended to stop glucarpidase dosing, and patients should be observed and appropriate supportive care should be instituted.

Properties/Effects

ATC code

V03AF09

Mechanism of action

Glucarpidase is a recombinant bacterial enzyme that hydrolyses the carboxyl-terminal glutamate residue from folic acid and structurally related molecules such as MTX. Glucarpidase converts MTX to its inactive metabolites DAMPA and glutamate. Because both DAMPA and glutamate are metabolised by the liver, glucarpidase provides an alternative route for MTX elimination in patients with renal dysfunction during high-dose MTX therapy.
Due to its large molecular size, glucarpidase does not cross the cellular membrane and therefore does not counteract the intracellular antineoplastic effects of high-dose MTX.

Pharmacodynamics

No data available.

Clinical efficacy

The efficacy of glucarpidase has been evaluated in four open-label, multi-centre, compassionate use, single-arm studies in patients with delayed MTX elimination due to renal dysfunction. The primary endpoint in the clinical studies was referred to as a clinically important reduction (CIR) in MTX concentration and was based on central laboratory MTX HPLC data. A patient was considered to have achieved a CIR if all centrally analysed MTX HPLC plasma concentrations after the first dose of glucarpidase were ≤1 µmol/L. A total of 476 patients received at least one dose of glucarpidase, and of these 169 patients (male and female patients, median age 20 years, range 0–84 years) had at least one central HPLC measurement of the MTX concentration after their first dose of glucarpidase and could be included in the pooled centrally analysed MTX HPLC population. These patients received a median initial dose of 50 units/kg (range 11 to 60 U/kg). A CIR was achieved by 61.5% (95% CI: 54.0% to 68.5%) of patients and was sustained for up to 8 days. A median reduction of >98% in MTX concentration occurred within 15 minutes following glucarpidase administration.
Rebound (defined as MTX concentration increase of at least 1 µmol/L and at least two times the post-glucarpidase nadir) occurred in 19.4% of patients in the centrally analysed MTX HPLC population.
Of the 410 patients in the pooled renal evaluable population (locally and centrally measured patients who had at least one post-glucarpidase renal function assessment) who developed serum creatinine (sCr) common toxicity criteria grade ≥2 at pre-glucarpidase baseline, 262 (63.9%) recovered to grade 0 or 1.

Children and adolescents

The pooled clinical safety database for glucarpidase includes data for 232 patients up to 17 years of age. Within the centrally analysed MTX HPLC population, 0% (0/1) of patients aged ≥28 days to <2 years (infant subgroup), 31.3% (5/16) of patients aged ≥2 to <12 years (child subgroup) and 49.1% (27/55) of patients aged ≥12 to <18 years of age achieved a CIR. A median reduction of ≥95% in MTX concentration occurred within 15 minutes following glucarpidase administration in all paediatric subgroups.

Pharmacokinetics

Absorption

The pharmacokinetics of glucarpidase in the absence of MTX were studied in 8 healthy subjects following glucarpidase 50 units/kg administered as an intravenous injection over 5 minutes. Serum glucarpidase activity levels were measured by an enzymatic assay and serum total glucarpidase concentrations were measured by enzyme linked immunosorbent assay (ELISA). The mean maximum serum concentration (C_{max}) was 3.3 µg/mL and the mean area under the curve (AUC_{0-INF}) was 23.3 µg·h/mL. The pharmacokinetic parameters derived from the serum total glucarpidase concentrations were similar to those generated by serum glucarpidase activity levels except for elimination half-life as described below.
A clinically relevant accumulation of glucarpidase after a repeat injection within an MTX cycle has not been observed.

Distribution

The mean volume of distribution (V_d) was 3.55 L.

Metabolism

The product is an enzyme, and therefore a protein. These products are metabolised into small peptides and individual amino acids and, therefore, the metabolic pathways are generally understood. Classical biotransformation studies are therefore not required and have not been conducted.

Elimination

Serum glucarpidase activity levels declined with a mean elimination half-life ($t_{1/2}$) of 5.6 hours and serum total glucarpidase concentration declined with a mean $t_{1/2}$ of 9 hours. The mean systemic clearance (CL) was 7.5 mL/min.

Kinetics in specific patient groups

Patients with renal impairment

A study of the pharmacokinetics of glucarpidase in the absence of MTX in 4 patients with severe renal impairment (CLcr <30 mL/min) showed that the mean pharmacokinetic parameters were similar to those observed in healthy subjects.

On this basis, no dose adjustment of glucarpidase is recommended for patients with renal impairment.
Children and adolescents
No formal evaluation of the effect of age on the pharmacokinetics of glucarpidase has been performed.

Preclinical data

Generally, preclinical effects were only observed at exposures considered sufficiently in excess of the maximum human exposure, indicating little relevance to humans.
The carcinogenic, genotoxic and reproductive toxicity potentials of glucarpidase have not been studied.
Decreased platelets were observed in a 14-day dog study, and intravenous human equivalent doses of 278 and 1389 units/kg were associated with increasing, severe dose-related toxicity which resulted in deaths or premature euthanasia.

Other information

Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products (see "*Instructions for handling*" section).

Shelf life

Do not use this medicine after the expiry date marked as "EXP" on the container.
In-use stability following reconstitution
Chemical and physical in-use stability following reconstitution has been demonstrated for 24 hours at 2–8ºC. From a microbiological point of view, Voraxaze should be administered immediately after reconstitution. If the ready-to-use solution is not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should normally not be longer than 24 hours at 2 to 8°C unless reconstitution has taken place in controlled and validated aseptic conditions.

Special precautions for storage

Store in the refrigerator (2-8°C), do not freeze, and keep out of the reach of children.
For storage conditions after reconstitution of the medicinal product, see "Shelf life" section.

Instructions for disposal

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

Authorisation number

70288 (Swissmedic)

Packs

1 vial with powder (1000 units) [A]

Marketing authorisation holder

Curatis AG, 4410 Liestal, Switzerland

Date of revision of the text

May 2026