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Public Summary SwissPAR dated 08.04.2022

Solmucol Bronchoprotect® (active substance: bacterial lysate from *Staphylococcus aureus, Streptococcus pyogenes, Streptococcus (viridans) oralis, Klebsiella pneumoniae, Klebsiella ozaenae, Haemophilus influenzae, Neisseria catarrhalis, Streptococcus pneumoniae*)

First authorisation in Switzerland: 6 January 2022

Medicinal product (sublingual tablet) to prevent recurrent respiratory tract infections in adults and children 3 years and older

Information on authorisation

The medicinal product Solmucol Bronchoprotect contains bacterial lysate from *Staphylococcus aureus, Streptococcus pyogenes, Streptococcus (viridans) oralis, Klebsiella pneumoniae, Klebsiella ozaenae, Haemophilus influenzae, Neisseria catarrhalis, Streptococcus pneumoniae* as its active substance.

It is a tablet to be taken sublingually, i.e. the tablet is placed beneath the tongue until fully dissolved.

Solmucol Bronchoprotect has been authorised in Switzerland to prevent recurrent respiratory tract infections in adults and children 3 years and older.

Solmucol Bronchoprotect was approved under a simplified authorisation procedure according to Art. 14 para. 1 let. a^{bis} of the Therapeutic Products Act (TPA). The TPA enables certain categories of medicines to be authorised according to a simplified procedure, provided this is compatible with the quality, safety and efficacy requirements and there is no conflict with Swiss interests or international obligations.

The authorisation of Solmucol Bronchoprotect is based on the medicinal product Ismigen, which contains the same active substance and has been authorised for a comparable indication, dosage and use in Poland for more than 10 years.

Swissmedic assessed the quality data on the active substance and finished product but did not conduct its own comprehensive scientific review for other aspects. Efficacy and safety were only reviewed in summarised form.

The requirements for issuing a complete SwissPAR (Swiss Public Assessment Report) and the resulting Public Summary SwissPAR have therefore not been met. Swissmedic refers to the authorisation of the foreign comparator medicinal product: https://www.ema.europa.eu

Further information on simplified authorisation according to Art. 14 TPA can be found in the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA).

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Solmucol Bronchoprotect®

Information for patients (package leaflet): Information for patients Solmucol Bronchoprotect®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.