Composition

10 g gel contains tromantadine hydrochloride 0.1 g.

Excipients: Methyl-4-hydroxybenzoate, lactose, sorbitol liquid (non crystallising), sorbic acid, hydroxyethyl-cellulose and purified water.

Indications

For the relief of the initial symptoms of recurrent herpes simplex, particularly pain and itching, but only before the stage of blister formation.

Contraindications

Hypersensitivity to tromantadine hydrochloride, methyl 4-hydroxybenzoate or any of the excipients. Viru-Merz Gel must not be used if hypersensitivity reactions have been observed after previous treatment with tromantadine, or in the presence of the following conditions:

- herpes simplex after the appearance of the vesicles, especially if these have already burst.

Pregnancy and Lactation

Pregnancy: Sufficient experience on use during pregnancy is not yet available. Animal experiments did not reveal any embryotic/teratogenic effects.

Lactation: It is not known whether the substance can pass into the milk.

Side Effects

During treatment with Viru-Merz Gel, skin reactions due to hypersensitivity (contact dermatitis) may occur, even if the product was previously well tolerated. These are characterised by an apparent worsening of the symptoms of herpes infection, such as aggravated itching, an increased sensation of pain and tension, increased reddening of the skin and nodule formation. In isolated cases, superinfection and abscess formation have been observed. Based on the results of numerous investigations, the frequency of proven tromantadine contact dermatitis is well under 1%. If contact dermatitis is suspected, an epidermal test with tromantadine should be performed by an allergy specialist, at the earliest 4 weeks after discontinuation of treatment.

Special warnings and precautions:

It is difficult to distinguish between possible contact allergy occurring at the site of treatment and the underlying herpes infection itself. This may mislead patients into undertaking additional local treatment of the apparently worsening herpes simplex. In isolated cases, superinfection and abscess formation have been observed. In such cases, use of Viru-Merz Gel must be stopped. Methyl p-hydroxybenzoate may cause allergic reactions (possibly delayed). Sorbic acid may cause local skin reactions (e.g. contact dermatitis).

Dosage and Administration

Unless prescribed otherwise, apply enough gel to the affected skin regions to cover the entire herpes focus and rub in gently. Repeat 3-5 times a day and if necessary more often. Administration of Viru-Merz Gel may only be continued until blisters occur (approximately 2-3 days). Administration must be immediately discontinued if, during treatment, existing symptoms worsen or new lesions occur.