centoreze tablets

Pelargonium root dry extract 20 mg

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Centoreze tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 20 mg of extract (as dry extract) from Pelargonium root

(*Pelargonium sidoides* DC and/or *Pelargonium reniforme* Curt. (4-25:1)

Extraction solvent: Ethanol 11% (m/m).

For a full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet

Red-brown, smooth round, biconvex

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Traditional herbal medicinal product used to relieve the symptoms of upper respiratory tract infections including the common cold, such as sore throat, cough and blocked or runny nose, based on traditional use only.

4.2 Posology and method of administration

For oral use only.

Adult, elderly and adolescents above 12 years of age:

Take 1 tablet three times daily (morning, midday, evening).

Tablets should be swallowed whole with a little water. The tablets should not be chewed.

The use in children under 12 years of age is not recommended *(see section 4.4 "Special warnings and precautions for use")*

Duration of use:

After relief of symptoms, it is recommended to continue treatment for a further 2-3 days in order to prevent a relapse. However, treatment duration should not exceed 10 days.

If the symptoms worsen, or persist after 7 days, a doctor or a qualified health care practitioner should be consulted.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Severe hepatic or renal disease.

4.4 Special warnings and precautions for use

Do not exceed the stated dose

A doctor or qualified healthcare practitioner should be consulted if symptoms worsen, or do not improve after one week.

If fever, shortness of breath or blood in the sputum occurs, a doctor or qualified healthcare practitioner should be consulted.

Hepatotoxicity and hepatitis cases were reported in association with the administration of the medicinal product.

Patients should stop taking this product immediately and consult their doctor if they develop signs and symptoms that suggest liver dysfunction (fatigue, anorexia, yellowing of the skin and eyes or severe stomach pain with nausea and vomiting or dark urine).

The use in children under 12 years of age has not been established and medical advice should be sought.

4.5 Interaction with other medicinal products and other forms of interaction

None reported.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. Due to lack of sufficient data, the use during pregnancy and lactation is not recommended.

No studies on the effect on fertility have been performed.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

4.8 Undesirable effects

The following adverse reactions have been reported.

Gastrointestinal complaints such as stomach pain, heartburn, nausea, vomiting, dysphagia or diarrhoea may occur uncommonly.

Mild bleeding from the gums or nose and hypersensitivity reactions (e.g. exanthema, urticaria, pruritus of skin and mucous membranes) have been reported in rare cases.

In very rare cases serious hypersensitivity reactions with swelling of the face, dyspnoea and decrease in blood pressure have been reported.

Hepatotoxicity and hepatitis have been reported. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare practitioner should be consulted.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme website **www.mhra.gov.uk/yellowcard** or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

No case of overdose has been reported.

Symptomatic and supportive measures should be taken as appropriate.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required as per Article 16c (1) (a) (iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties

Not required as per Article 16c (1) (a) (iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

The extract was negative in an Ames test for mutagenicity.

Tests on reproductive toxicity and carcinogenicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Extract:
Maltodextrin

Tablet core:
Cellulose powder
Cellulose, microcrystalline
Silica, colloidal anhydrous
Magnesium stearate

Film coating:
Hypromellose
Macrogol, type 6000
Iron oxide yellow E172
Iron oxide red E172
Calcium carbonate
Talc

6.2 Incompatibilities

Not applicable

6.3 Shelf life

5 years

6.4 Special precautions for storage

This product does not require any special storage conditions.

Store in the original packaging.

6.5 Nature and contents of container

This product is available in packs with 15, 21, 30 or 60 tablets.

The tablets are sealed into PVC/PVDC-aluminium blisters. The blisters are packed into folding cartons. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

DePlantis Ltd
Plough Lane
Hereford
HR4 0EL

8. MARKETING AUTHORISATION NUMBER(S)

THR 53449/0001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11th January 2022

10. DATE OF REVISION OF THE TEXT

3rd November 2022

If you would like further information about this product, please contact: DePlantis Limited, Plough Lane, Hereford HR4 0EL

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This leaflet was prepared in November 2022.