Translation from the German Language

Text of the Information intended to be used for the Expert Information

(= German type of Summary of Product Characteristics)

Expert Information

1. NAME OF THE MEDICINAL PRODUCT

Reparil coated tablets
20 mg, gastro-resistant coated tablets
For use in adults and children over 7 years of age
Active substance: aescin

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each gastro-resistant coated tablet contains:
Aescin 20 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gastro-resistant coated tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Localised swelling following injury

4.2 Posology and method of administration

Posology
Adults and adolescents aged 14 years and above initially take 2 tablets 3 times daily, as maintenance dose and in milder cases 1 tablet unchewed with some liquid after meals 3 times daily.

Children and adolescents
Children aged 7 to 14 years take 1 tablet unchewed with some liquid after meals 2 to 3 times daily.

Reparil coated tablets are not indicated in children under the age of 7 years.

Method of administration

The tablets are taken unchewed with some liquid after meals.

4.3 Contraindications

Reparil coated tablets must not be taken by patients with

- hypersensitivity to the active substance or to any of the excipients listed in section 6.1,
- renal insufficiency or renal diseases,
- pregnancy and breast-feeding.

4.4 Special warnings and precautions for use

Patients with rare hereditary (deficiency) problems of galactose intolerance, lactase deficiency, glucose-galactose malabsorption, fructose intolerance or sucrase isomaltase deficiency should not use Reparil coated tablets.

Children and adolescents
Reparil coated tablets are not indicated in children under the age of 7 years.

4.5 Interaction with other medicinal products and other forms of interaction

Administration of aescin can enhance the effect of anticoagulant medicinal products.

Concurrent use of aminoglycosides (e.g. gentamicin) should be avoided because an increase in the nephrotoxicity of aminoglycosides cannot be completely excluded.

The plasma protein binding of aescin can be inhibited by antibiotics. Cephalotin and ampicillin, for instance, raise the concentration of free aescin in the serum.

Therefore, concurrent administration of these medicinal products with Reparil coated tablets is not recommended.

4.6 Pregnancy and lactation

Reparil coated tablets should not be used during pregnancy because the product has only inadequately been tested in animal studies and no experience with pregnant women has been documented. Breast-feeding during treatment is not recommended, because it is not known to which extent the active substance passes into breast milk.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

The following convention has been used for the classification of side effects in terms of frequency:

Very common:	≥ 1/10
Common:	≥ 1/100 tp < 1/10
Uncommon:	≥ 1/1,000 to < 1/100
Rare:	≥ 1/10,000 to < 1/1,000
Very rare:	< 1/10,000
Not known:	Frequency cannot be estimated from the available data.

The following side effects are known for Reparil coated tablets:
Immune system disorders:
Very rare: hypersensitivity reactions (e.g. urticaria)

Gastro-intestinal disorders:
Uncommon: gastro-intestinal tract disorders

If hypersensitivity reactions occur, use of Reparil coated tablets should be discontinued.

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 Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn (Germany), Website: www.bfarm.de.

4.9 Overdose

No cases of overdose have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Capillary stabilizing agents

ATC Code: C05CA07

The site of action of aescin is the vascular wall. In case of abnormally raised permeability, aescin inhibits exsudation by reducing extravasation of fluid into the tissue and accelerating reabsorption of the existing oedema. The mechanism of action is based on a change in the permeability of the capillary openings involved. Furthermore, aescin promotes capillary resistance, inhibits inflammatory processes and improves microcirculation.

5.2 Pharmacokinetic properties

After oral administration of tritium-labelled aescin, a mean 12 – 16% of the applied activity was absorbed from the intestinal tract in mice and rats. Excretion occurs via the bile as well as the urine. The metabolisation rate is higher after oral administration than after intravenous injection. Organ distribution is negligibly low in the excretory organs liver and kidneys in comparison to the higher values in the blood.

5.3 Preclinical safety data

Aescin was only inadequately tested in animal experiments. In these experiments it proved to be moderately to highly toxic. Nephrotoxic changes were particularly significant. Complete testing for mutagenicity produced no evidence of mutagenic effects. No carcinogenicity studies have been carried out.
Aescin was inadequately tested for reproductive toxicity. After oral administration of aescin in mice and rabbits during organogenesis embryotoxic effects occurred (reduced fetal weights, delayed skeleton ossification, in higher doses embryo lethality). No effects on the viability of offspring with prenatal exposure were found.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate, Povidone (K29-32), Magnesium stearate (Ph. Eur.), Sucrose (sugar), Talc, Gum arabic, Titanium dioxide E 171, Colloidal anhydrous silica, Poly(ethyl acrylate, methacyrylic acid), Macrogol 8000, Sodium hydroxide, Carmellose sodium, Triethyl citrate, Simeticone emulsion, Bleached wax, Carnauba wax.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years

6.4 Special precautions for storage

No special storage conditions are required for this medicinal product.

6.5 Nature and contents of container

PVC and printed aluminium blister packs in strips of 10 coated tablets

Packs of 20, 50 or 100 coated tablets

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

MEDA Pharma GmbH & Co. KG
Benzstrasse 1
61352 Bad Homburg (Germany)
Phone: (06172) 888-01
Fax: (06172) 888-27 40
E-Mail: medinfo@medapharma.de

8. MARKETING AUTHORISATION NUMBER

6093088.00.00

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

22 December 2005

10. DATE OF REVISION OF THE TEXT

April 2015