Instructions for use

# Reparil 20 mg Tablets

MADAUS

**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. Nevertheless you still need to use Reparil enteric coated tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

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**In this leaflet:**



**Reparil enteric coated tablets**
active ingredient: amorphous aescin
enteric coated tablets

- The active substance is escin. 1 enteric coated tablet contains 20 mg amorphous aescin.
- The other ingredients are lactose-monhydrate, povidone, magnesium stearate, sucrose, talc, acacia, titanium dioxide (E 171), colloidal anhydrous silicea, poly(ethyl acrylate, methacrylic acid), macrogol 8000, sodium hydroxide, carmellose sodium, triethyl citrate, simethicone emulsion, Carnauba wax and white beeswax.
- Aescin is derived from horse chestnut (Aesculus hippocastanum)

Pack sizes: Box of 20, 50 or 100 enteric coated tablets.
Reparil 20 mg coated tablets are round biconvex white, glossy coated tablets of 7 mm in diameter

## 1. What Reparil enteric coated tablets ARE AND WHAT THEY ARE USED FOR / INDICATION

1.1 Reparil coated tablets have decongestant effect in case of injuries.

1.2

**Product Registration Holder:**
Mylan Healthcare Sdn. Bhd.,
15-03 & 15-04, Level 15, Imazium,
No. 8, Jalan SS 21/37, Damansara Uptown,
47400 Petaling Jaya,
Selangor, Malaysia.

**Manufacturer:**
Madaus GmbH,
Lütticher Straße 5,
53842 Troisdorf,
Germany.

1.3. Reparil enteric coated tablets are indicated for reduction of localised swelling following injuries.

## 2. BEFORE YOU TAKE Reparil enteric coated tablets

**2.1. Do not take Reparil enteric coated tablets**
- with known hypersensitivity against aescin or any of the excipients,
- with renal insufficiency / renal failure or kidney diseases.

**Pregnancy:**
Reparil enteric coated tablets should not be taken during pregnancy, because animal studies are insufficient with respect to effects on pregnancy and / or embryonal / fetal development. Experience with the administration in pregnant women is not documented.

**Breast-feeding:**
Since it is unknown to which extent the active ingredient is passed into breast-milk, breast-feeding should not be done during the reatment.

**2.2 Special caution before you take Reparil enteric coated tablets**

**Children:**
Reparil enteric coated tablets are not indicated for children under 7 years of age.

**Pregnancy and breast feeding:**
See above

**Driving and using machines:**
No restrictions.

**Important information about some of the ingredients of Reparil enteric coated tablets / Warnings and Precautions**
Patients suffering from the rare hereditary galactose intolerance, lactase deficiency, glucose-galactose malabsorption, fructose intolerance or saccharase-isomaltase deficiency should not take Reparil enteric coated tablets because of their contents of lactose and sucrose.

**2.3. Interaction with other medicines**

**Using other medicines:**
The effects of anticoagulants may be enhanced by aescin.
The concomitant administration of antibiotics of the aminoglycoside type (e.g. gentamicin) should be avoided, since it can not totally be ruled out that their nephrotoxicity may be enhanced.
The binding of escin to plasma proteins may be affected by antibiotics. Cephalotin and ampicillin, e.g., cause a rise in the concentration of free serum aescin.
The substances mentioned should therefore not be administered concomitantly to Reparil enteric coated tablets.

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| Description | Reparil 20 mg, 50 | | | Date: 06/02/2025 | | Time: 18:24 | |
| Component Type | Leaflet | Site Barcode/ DataMatrix | Laetus Code 120 | No. of colours | 1 | Page Count | 1 of 2 |
| Affiliate Item Code | 3652988 | Viatris SAP No. | 400559164 | Colours | Black | | |
| Superseded Affiliate Item Code | 3092426 | Vendor Job No. | Typopharma #153198 | Non-Print Colours | Keyline | | |
| TrackWise/GLAMS Job No. | 3652988 | Artwork Proof No. | 2 | | | | |
| MA No. | MAL11030107X | Client Market | Malaysia | Equate CMYK with | | | |
| Supplier SAP No. | n/a | Barcode Info | n/a | | | | |
| New Supplier Code | 50100269 | 3D Render ID | n/a | Main Font | Helvetica Neue LT Pro | Body Text Size | 8 pt |
| Superseded Supplier Code | 709456 | PC | n/a | Dimensions | 194 x 320 mm | Min Text Size used | 8 pt |
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| Sign-offs | | | | | | | |
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### 3. DOSAGE / DIRECTIONS

Always use Reparil enteric coated tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

3.1 Kind of application: oral use

3.2 If not otherwise prescribed: as an initial dose, adults and adolescents over 14 years should take 2 tablets 3 times daily after meals with some fluid. In milder cases, or as a maintenance dose, they should take 1 tablet 3 times daily.

Children between 7 and 14 years of age should take 1 tablet 2 or 3 times daily after meals with some fluid.

Treatment should be continued for two to three months.

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### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Reparil enteric coated tablets can have side effects.

For the evaluation of undesirable effects, the following terms of frequency are used:

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| very common: | more than 1 of 10 patients |
| common: | less than 1 of 10 patients, but more than 1 of 100 patients |
| uncommon: | less than 1 of 100 patients, but more than 1 of 1,000 patients |
| rare: | less than 1 of 1,000 patients, but more than 1 of 10,000 patients |
| very rare: | less than 1 of 10,000 patients, including isolated reports |

4.1. Side effects of Reparil enteric coated tablets:
In very rare cases, hypersensitivity reactions, like urticaria, can occur. Disorders of the gastrointestinal tract are uncommon.

4.2. Counter measure:
In case hypersensitivity reactions occur intake of Reparil enteric coated tablets should be discontinued.

4.3. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### 5. Common Pharmacological Properties of Aescin

#### 5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: capillary-stabilising agents, ATC code: C05CA

The targe site of amorphous aescin is the vascular wall. In pathologically raised permeability, amorphous aescin inhibits exudation by reducing the extravasation of fluid into the tissue and accelerating the subsidence of oedema. The mode of action is based on changes in the permeabililty of the affected capillary walls. In addition, amorphous aescin raises capillary resistance, inhibits inflammatory processes and improves microcirculation.

#### 5.2 Pharmacokinetic Properties

The metabolism of oral administered amorphous aescin was studied in rats and mice. After oral administration of tritium-marked amorphous aescin, the administered activity absorbed from the gastro-intestinal tract averaged 12% to 16%. Excretion occurs by both, bile and urine. The rate of metabolisation is bigger following oral administration than with intravenous application. The organ distribution of amorphous aescin is insignificant in the excretion organs liver and kidneys, compared to the increased blood level.

#### 5.3 Toxicological Properties/Overdosage

Cases of overdose have not been reported.
Toxicologic properties: After 24 to 48 hours, an overdose with aescin leads to excitation and anxiety, diarrhoea and vomiting, mydriasis, delirium and death due to respiratory paralysis, especially in children.
Countermeasures: elimination of the poison (gastric lavage with KMnO4 solution, medicinal charcoal), correction of the water and electrolyte balance, monitoring of renal function, administration of anticonvulsants and antispasmodics. Acute toxicity: Humans: The acute I.V. toxicity of aescin varies among species between 2.0 and 15.2mg/kg. Toxicity is due to acute nephrotic conditions and can precipitate the clinical picture of fatal uraemia within 24 to 48 hours.
Chronic toxicity: Humans: Late toxicity has never been observed. b-aescin is tolerated very well by humans. The differences in toxicity between aescin and total horse chestnut extracts are of minor importance. The therapeutic window cannot be increased by freedom from saponins.

### 6. STORAGE CONDITIONS

Keep out of the reach and sight of children.

Avoid storing product in direct sunlight. Store below 30 degrees Celcius.

The expiry date is printed on the folding carton and on the tube. Do not use this pack after the expiry date has passed.

**This leaflet was last revised in Feb 2025**

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