Package leaflet: Information for the user

Rapydan 70mg/70mg medicated plaster

Lidocaine/Tetracaine

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Rapydan is and what it is used for

Rapydan contains two local anaesthetics – lidocaine and tetracaine. These medicines are used to numb a small area of skin before a procedure that might be painful, such as an injection or a minor surgical procedure.

2. Before you use Rapydan

Do not use Rapydan
- if you are allergic (hypersensitive) to lidocaine, tetracaine or sodium borate or any of the other ingredients of Rapydan (see section 6).
- if you are allergic (hypersensitive) to other local anaesthetics.
- if you are allergic (hypersensitive) to para-aminobenzoic acid, a compound that is formed when your body breaks down tetracaine.

Do not use Rapydan on broken or damaged skin or on mucous membranes, e.g. inside the mouth or nose.

Take special care with Rapydan
Tell your doctor or pharmacist
- if you have problems with your liver, kidney or heart.
- if you are very unwell or in poor physical condition, because you may be more sensitive to the effects of lidocaine and tetracaine.

Rapydan should be used with caution close to the eyes. If Rapydan comes into contact with your eye, immediately rinse your eye with water or salt solution and protect it until feeling returns.

Rapydan contains a heat-releasing component that may reach a maximum temperature of up to 40°C, with an average temperature of 26-34°C.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The risk of side effects increases if Rapydan is used at the same time as some other medicines, e.g.
- some medicines for treatment of heart conditions such as quinidine, disopyramide, tocainide, mexiletine and amiodarone.
- other medicines containing lidocaine and/or tetracaine.

Pregnancy and breast-feeding
The use of Rapydan may be considered during pregnancy and lactation, as advised by your doctor.
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Rapydan has no influence on the ability to drive and use machines.

Important information about some of the ingredients of Rapydan
Rapydan contains methyl parahydroxybenzoate (E 218) and propyl parahydoxybenzoate (E 216), which may cause allergic reactions (possibly delayed).

3. How to use Rapydan

Always use Rapydan according to the doctor's instructions. Ask a doctor or pharmacist if you are unsure of anything.

Rapydan is applied to clean dry skin for 30 minutes. For detailed instructions, see "Instructions for use" below.

Rapydan should be used immediately once the sachet has been opened. Rapydan can only be used once.

Rapydan also contains a heating component (CHADD heating pod) which raises the skin temperature slightly (see section 2 Before You Use Rapydan). The heating component needs oxygen to make it work so the plaster is packaged in an air-tight pouch. This means as soon as the pouch is opened the plaster should be used immediately because it will start to gently heat up. It is important that the pouch is opened only when you are ready to use the medicated plaster.

Rapydan should not be used under occlusive dressings due to the heat-releasing nature of the plaster.

Adults
1 or at most 4 plasters at the same time. Do not use more than 4 plasters in a day (24 hours).

Children and adolescents (older than 3 years of age)
1 or at most 2 plasters at the same time. Do not use more than 2 plasters on a child in a day (24 hours).

Do not use on children under 3 years of age.

INSTRUCTIONS FOR USE
1. Make sure the skin is clean and dry.
2. Open the heat-sealed film sachet and remove the plaster.
3. Remove the plastic tray from the plaster. Do not touch the white round pad that contains the medicines.
4. Apply the plaster so that the white, round pad containing the medicines covers the area to be treated.
5. Press firmly only around the edges of the medicated plaster to ensure that the medicated plaster sticks well to the skin.
6. Press gently on the centre of the plaster to ensure that the medicines come into contact with the skin.
7. Take note of the time of application. Rapydan must be applied for 30 minutes before any procedures are carried out. Care should be taken that the medicated plaster does not fall off during this time.
8. Remove the plaster and clean the area thoroughly before the procedure. If applying the plaster before a procedure to be performed by a doctor, let the doctor remove the plaster, unless instructed otherwise.

After Rapydan has been removed
Rapydan numbs the area of skin treated so that feeling is reduced. To avoid any accidental damage, take care not to scratch or rub the numbed area or touch very hot or cold surfaces until complete sensation has returned.

If you use more Rapydan than you should
If the plaster is left on the skin for longer than recommended, or if more than the recommended number of plasters are used, the risk of serious side effects increases.

Overdose of Rapydan is unlikely with normal use. However, if you absorb too much of the active substances, or if for example, a child absorbs the active substances by mistake, contact your doctor or local Accident and Emergency department for help.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Rapydan can have side effects, although not everybody gets them.

The plaster may cause allergic (anaphylactoid) reactions such as skin rash, swelling and breathing difficulties. **If you experience any of the above side effects you must remove the plaster immediately and contact a doctor.**

Most side effects are local and occur at the site where the plaster has been placed. They are generally mild, only last for a short time and usually go away after the end of treatment.

Tell your doctor or pharmacist if any of the following side effects become troublesome.

Very common side effects (affecting more than 1 in 10 treated patients):
- redness where the plaster has been applied
- pallor of the skin
- swelling

Common side effects (affecting fewer than 1 in 10 treated patients):
- rash

Uncommon side effects (affecting fewer than 1 in 100 treated patients):
- rash with blisters
- itching

Rare side effects (affecting fewer than 1 in 1000 treated patients):
- nettle rash or rash with spots
- discoloration of the skin
- pain
- change in taste sensation

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Ireland
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971, Fax: +353 1 6762517. Website: www.hpra.ie. e-mail: medsafety@hpra.ie.

United Kingdom

Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rapydan

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the sachet and carton after "EXP".

Do not store above 25°C.

Do not use Rapydan if you can see that the packaging is damaged in any way.

Used plasters should be folded together with the sticky side inwards, and disposed of safely so that children cannot get at the plaster. Any unused product or waste material should be disposed of in accordance with local requirements. Unused medicine should not be flushed down the toilet or thrown into household waste. Ask at the pharmacy what you should do with medicine that is no longer used. These measures are to protect the environment.

6. Further information

What Rapydan contains

- The active substances in each medicated plaster are 70 mg lidocaine and 70 mg tetracaine.
- Plaster consists of:
  - Backing layer: polyethene film, covered on one side with acrylate adhesive
  - Controlled Heat Assisted Drug Delivery (CHADD) heating pod: iron powder, activated carbon, sodium chloride, and wood flour, encapsulated in a filter paper pouch
  - Adhesive film: polyethene and acrylate adhesive
  - Heat sealable foil: polyethene and aluminium laminate, covered with polyester urethane adhesive
  - Drug layer: polyvinyl alcohol, sorbitan monopalmitate, purified water, methyl parahydroxybenzoate (E 218), propyl parahydroxybenzoate (E 216), sodium borate-covered fibre coating
  - Plastic (polyethylene) tray, which is removed before using the plaster

What Rapydan looks like and contents of the pack

Oval, light brown medicated plaster (approximate dimensions: 8.5 cm x 6.0 cm), with a removable opaque plastic tray.

The plasters are packed individually in protective sachets (polyester/aluminium/polythene laminate).
Pack sizes: 1, 2, 5, 10, 25 or 50 plasters.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Eurocept International BV, Trapgans 5, 1244 RL Ankeveen, Netherlands

This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member State	Name of the medicinal product
Austria / Germany	Rapydan 70 mg/70 mg wirkstoffhaltiges Pflaster
Belgium / Luxembourg	Rapydan® 70 mg/70 mg emplâtre médicamenteux Rapydan® 70 mg/70 mg medicinale pleister Rapydan® 70 mg/70 mg wirkstoffhaltiges Pflaster

Denmark	Ralydan 70 mg/70 mg medicinsk plaster
Greece/Cyprus	Rapydan 70mg/70mg φαρμακούχο έμπλαστρο
Hungary	Velocaine 70 mg/70 mg gyógyszeres tapasz
Ireland / United Kingdom	Rapydan 70/70 mg medicated plaster
Italy	Ralydan 70 mg/70 mg cerotto medicato
Netherlands	Rapydan 70 mg/70 mg medicinale pleister
Norway	Rapydan 70 mg/70 mg medisinert plaster
Poland	Rapydan: 70 mg + 70 mg plaster leczniczy
Portugal	Rapydan 70mg/70mg, emplastro medicamentoso
Sweden	Rapydan 70mg/70mg medicinskt plåster

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