

Package Leaflet: Information for the user
Pedamed 100mg/g Cream
Zinc undecylenate

Please read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again
- If you need more information or advice, please ask your doctor or pharmacist
- You must contact your doctor if your symptoms get worse or do not improve
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Pedamed Cream is and what it is used for
2. Before you use Pedamed Cream
3. How to use Pedamed Cream
4. Possible side effects
5. How to store Pedamed Cream
6. Further information.

1. What Pedamed 100mg/g Cream is and what it is used for

Pedamed Cream contains the active ingredient zinc undecylenate. Zinc undecylenate is an antifungal which works by preventing fungal growth that can cause skin infections.

Pedamed Cream is used for the treatment and prevention of athlete's foot and other fungal skin infections. It is also used to remove foot odours and to stop feet from sweating.

Pedamed Cream is for use on the skin only.

2. Before you use Pedamed 100mg/g Cream

Do not use Pedamed Cream if you are allergic to zinc undecylenate or to any of the other ingredients listed (see ingredients section).

Take special care with Pedamed Cream if your skin is damaged - do not use it on areas of broken skin.

If any of the above applies to you, please talk to a doctor or pharmacist before using this medicine.

Taking other medicines:

Always tell your doctor or pharmacist about all the medicines you are taking. This means medicines you have bought yourself as well as those you have on prescription from your doctor.

Pregnancy and breast-feeding:

Please let your doctor or pharmacist know if you are pregnant or breast feeding or planning on getting pregnant. If you become pregnant whilst you are using Pedamed Cream, tell your doctor.

Driving and using machines:

Pedamed Cream does not affect your ability to drive and operate machinery.

Important information about some of the ingredients:

- Contains the preservatives ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216) and methyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).
- Contains bronopol which may cause local skin reactions such as contact dermatitis.

3. How to use Pedamed 100mg/g Cream

Read this section carefully to see how to use Pedamed Cream.

If Pedamed Cream has been prescribed for you by your doctor, follow any instructions he/she may have given you. If you purchased this product without a prescription, follow these directions closely:

- Pedamed Cream is for use on the skin only
- Do not get Pedamed Cream in your eyes, nose or mouth. If you get this medicine in your eyes, nose or mouth, rinse immediately with cool tap water
- Wash and dry your hands before and after using this medicine
- Clean and dry the affected area
- Apply a thin layer of Pedamed Cream over the affected area twice daily and rub the cream in gently. For athlete's foot apply the cream in between the toes as well
- Keep using Pedamed Cream for at least one week after all signs of infection have gone
- For the best results, Pedamed Cream should be used together with an antifungal powder such as Pedamed 100mg/g Cutaneous Powder
- To stop any reoccurrence of the infection, use regularly after showering and bathing.

If Pedamed 100mg/g Cream is used incorrectly:

If anyone accidentally swallows this medicine contact your doctor or go to your hospital casualty department as soon as possible. Take your medicine and pack with you.

If you forget to use Pedamed 100mg/g Cream:

If you forget to use Pedamed Cream don't worry. Apply the cream as soon as possible and then continue the rest of your treatment as usual. Do not apply this cream more than twice daily.

If your symptoms do not go away or you are not sure how to use this medicine and would like further information, then please contact your doctor or pharmacist.

4. Possible side effects

Like all medicines Pedamed Cream may sometimes cause side effects, although not everyone will get them. Skin irritation can occur occasionally when using this product.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971 Fax: +353 1 6762517.

Website: www.hpra.ie; E-mail: medsafety@hpra.ie By reporting side effects you can help provide more information on the safety of this medicine

5. How to store Pedamed 100mg/g Cream

Keep out of the reach and sight of children.

Do not store above 25°C. Keep the tube tightly closed.

Do not use Pedamed Cream after the expiry date which is stated on the carton and tube label after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Pedamed Cream contains

The active substance is zinc undecylenate. Each gram of cream contains 100mg zinc undecylenate equivalent to zinc undecylenate 10%w/w.

The other ingredients are zinc oxide, alum, allantoin, chlorhexidine hydrochloride, levomenthol, light liquid paraffin, white soft paraffin, sorbitol solution (70 per cent, non-crystallising), macrogol stearate, hydrogenated vegetable glyceride, ethyl, methyl and propyl parahydroxybenzoates (E214, E218, E216), bronopol, purified water.

What Pedamed Cream looks like and contents of the pack

Pedamed Cream is a smooth, white cream. This medicine is available in a pack size of 30g.

Product Authorisation Holder

Phoenix Healthcare Limited

Suite 12, Bunkilla Plaza, Bracetown Business Park, Clonee, County Meath, Ireland

Manufacturer

Ricesteele Manufacturing Limited

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If you would like this leaflet in a different format, please contact the product authorisation holder at the above address.