

PACKAGE LEAFLET: INFORMATION FOR THE USER

PYRALVEX™ Oromucosal Solution Rhubarb Extract and Salicylic Acid

MEDA



Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, 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 become serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

If you need the information on this leaflet in an alternative format, such as large text, or Braille please ring from the UK: 0800 198 5000.

In this leaflet:

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

1. What Pyralvex is and what it is used for

Pyralvex contains rhubarb extract (containing anthraquinone glycosides) and salicylic acid. The anthraquinone glycosides relieve inflammation and salicylic acid is an analgesic, which helps relieve pain.

Pyralvex is used to relieve pain associated with mouth ulcers and denture irritation.

2. Before you use Pyralvex

Do not give to children or adolescents under the age of 16 years. This is because there is a possible link between salicylates and Reye's syndrome when given to children. Reye's syndrome is a very rare disease which affects the brain and liver and can be fatal.

Do not use Pyralvex if you are allergic (hypersensitive) to rhubarb extract or salicylic acid or any of the other ingredients of Pyralvex.

For hygiene reasons, this pack must only be used by one person.

Taking/using 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.

Using Pyralvex with food and drink

Avoid rinsing your mouth or eating for 15 minutes after use.

Pregnancy and breast-feeding

Talk to your doctor before you use Pyralvex if you are pregnant or breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

Important information about some of the ingredients of Pyralvex

This medicinal product contains small amounts of ethanol (alcohol) less than 100 mg per dose.

3. How to use Pyralvex

Always use Pyralvex exactly as your doctor had told you.

In adults and the elderly Pyralvex should be applied liberally to the ulcer or irritated denture area (after dentures have been removed) 3 to 4 times a day using the brush provided.

Do not exceed the stated frequency of application as excess Pyralvex may be harmful.

Do not use for more than 7 days.

If you forget to use Pyralvex use it as soon as you remember. If your next dose is due only use that dose and do not use extra to make up for the missed dose.

If your symptoms do not improve consult your doctor. If you have any questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Pyralvex can cause side effects, although not everybody gets them.

Some people may have an allergic reaction which may include an itchy skin rash (nettle rash or hives.) If this occurs stop the treatment and contact your doctor.

Very commonly, a short-term burning feeling can occur when Pyralvex is used.

When using Pyralvex, a temporary discolouration of the teeth, denture and dental protheses (an artificial device that replaces one or more missing teeth), or mouth can also commonly occur, but this is easily removed during normal cleaning of the teeth.

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 the Yellow Card Scheme at: 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 Pyralvex

Keep all medicines out of the reach and sight of children.

Store below 25 °C.

Do not use Pyralvex after the expiry date which is stated on the bottle as month/year. The expiry date refers to the last day of the 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 Pyralvex contains

The active substances are Rhubarb extract and Salicylic acid. Each 1 ml of solution contains 50 mg rhubarb extract (equivalent to 5 mg anthraquinone glycosides) and 10 mg salicylic acid.

The other ingredients are ethanol and water.

What Pyralvex looks like and contents of the pack

Each carton contains an amber glass bottle containing 10 ml of liquid and an applicator brush.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is Meda Pharmaceuticals Ltd, Skyway House, Parsonage Road, Takeley, CM22 6PU. It is made by Norgine Pharma, 28102 Dreux, France.

The leaflet was last approved in November 2013.