1.3.2 PATIENT INFORMATION LEAFLET

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

This medicine is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use Paragoriese-Elikser 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 after 10 days.

SCHEDULING STATUS:

S2

PROPRIETARY NAME (and dosage form):

PARAGORIESE-ELIKSER (tincture)

WHAT THIS MEDICINE CONTAINS:

Each 5 ml of Paragoriese-Elikser contains Opium tincture 0,25 ml, Aniseed oil 0,015 ml, Camphor 14,97 mg and Benzoic acid 24,95 mg as active substances.

The other ingredients are:

Alcohol 58,5 % v/v and purified water.

WHAT THIS MEDICINE IS USED FOR:

This medicine is used to treat diarrhoea, abdominal pain and cough.

INSTRUCTIONS BEFORE TAKING THIS MEDICINE:

Do not give Paragoriese-Elikser to babies or children.

Do not take Paragoriese-Elikser:

- if you have diminished respiratory function, especially if there is excessive mucus in the lungs and a bluish discolouration of the skin and mucous membranes
- if you are suffering from acute alcoholism
- if you suffer from any convulsive disorders
- during an asthma attack.
- if you suffer from heart failure due to chronic lung disease.

Take special care with Paragoriese-Elikser:

Consult your doctor, pharmacist or other health care professional before taking this medicine:

- if you have an underactive thyroid, or suffer from a condition where the adrenal gland cannot produce an adequate amount of hormones needed by the body
- if you have impaired liver function
- if you have an enlarged prostate
- if you are suffering from shock

Pregnancy and breastfeeding:

If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Important information about some of the ingredients of Paragoriese-Elikser :

This product contains a high percentage of alcohol.

Taking other medicines with Paragoriese-Elikser :

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of Paragoriese-Elikser with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW TO TAKE THIS MEDICINE:

Follow your doctor's instructions if this medicine was prescribed, or alternatively follow the instructions in the leaflet.

Do not give this medicine to babies or children.

Do not share medicines prescribed for you with any other person.

For adults:

Take one to two medicine measures (5 ml to 10 ml) up to four times daily.

A calibrated dosage cup is included to make it easier to measure an accurate dosage.

If you have the impression that the effect of Paragoriese-Elikser is too strong or too weak, talk to your doctor or pharmacist.

If you take more of this medicine than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

Symptoms of overdosage may include diminished respiratory function, pinpoint pupils, a fall in body temperature and weak muscles.

POSSIBLE SIDE EFFECTS:

Paragoriese-Elikser can have side effects.

The most common side-effects are nausea, loss of appetite, constipation, confusion and sweating.

Other side-effects include dry mouth, flushing of the face, dizziness, a slowing of your heart rate, palpitations, light headedness, a state of calmness, restlessness and a change in your mood.

If you take Paragoriese-Elikser on a regular basis, you may become dependant on this medicine.

If you experience any of the symptoms listed above, the use of this medicine must be stopped.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSAL INFORMATION:

To store this medicine:

- Keep all medicines out of the reach and sight of children.
- Store below 25 ºC and keep the container tightly closed in order to protect the medicine from moisture.
- Do not store this medicine in the bathroom, near the kitchen sink, or in other damp places where it might be affected by moisture.
- Do not keep outdated medicine or medicine no longer needed. Be sure that any discarded medicine is out of the reach of children.

PRESENTATION:

Liquid in 20 ml clear plastic bottles.

IDENTIFICATION:

A bright, brown liquid with the odour of camphor.

REFERENCE NUMBER:

B888 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Pharmacare Limited

Building 12 Healthcare Park

Woodlands Drive

Woodmead 2148

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