1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0

DUIWELSDREKDRUPPELS 1 g per 5 ml drops

Asafoetida, ethanol

Sugar free

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

DUIWELSDREKDRUPPELS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use DUIWELSDREKDRUPPELS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DUIWELSDREKDRUPPELS with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after a few days.

What is in this leaflet

1. What DUIWELSDREKDRUPPELS is and what it is used for
2. What you need to know before you take DUIWELSDREKDRUPPELS
3. How to take DUIWELSDREKDRUPPELS
4. Possible side effects
5. How to store DUIWELSDREKDRUPPELS
6. Contents of the pack and other information

1. What DUIWELSDREKDRUPPELS is and what it is used for

DUIWELSDREKDRUPPELS contains the active substances asafoetida and ethanol.

DUIWELSDREKDRUPPELS is indicated in adults for:

- relieving excessive amounts of air or gas from the stomach which would normally cause an uncomfortable bloated or distended feeling;
- helping to make coughing of phlegm easier (expectorant action) in the treatment of dry coughs associated with bronchitis.

2. What you need to know before you take DUIWELSDREKDRUPPELS

Do not take DUIWELSDREKDRUPPELS:

- if you are hypersensitive (allergic) to asafoetida or any of the other ingredients of DUIWELSDREKDRUPPELS (listed in section 6);
- if you have porphyria;
- if you are a recovering alcoholic;
- if you are taking medicine to stop you from drinking alcohol (disulfiram / “Antabuse”);
- if you are pregnant or breastfeeding your baby.

Do not give DUIWELSDREKDRUPPELS to children.

Warnings and precautions

DUIWELSDREKDRUPPELS contains a high percentage of alcohol. This may cause a number of unwanted reactions in your body, especially are you are pregnant or breastfeeding

your baby. It can also increase the side effects of several other medicines you may be taking.

Take special care with DUIWELSDREKDRUPPELS:

- if you suffer from peptic ulcer disease, epilepsy or diabetes mellitus;
- if you have liver problems;
- if you are a recovering alcoholic.

Other medicines and DUIWELSDREKDRUPPELS

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Central nervous system (CNS) depressants (e.g. hypnotics (sleeping pills)), antihistamines (for allergies), opioids (strong painkillers), antiepileptics (medicines for epilepsy), antidepressants (for depression), sedatives (for anxiety).
- Antidiabetics (e.g. sulfonylurea, insulin, chlorpropamide): medicines used to treat or control high blood sugar (diabetes).
- Antihypertensives (e.g. vasodilators, verapamil): medicines used to treat high blood pressure .
- Indoramin: medicine used to treat prostate problems (benign prostatic hyperplasia).
- Painkillers (e.g. aspirin, diclofenac): medicine used to treat pain.
- Oral anticoagulants (e.g. warfarin): medicines used to prevent your blood from forming blood clots.
- Vasopressin: a hormone that regulates and balances the amount of water in your blood.

- Antimicrobials (e.g. nitro-imidazoles, metronidazole, nifuratel, cephalosporins, griseofulvin, furazolidone, mepacrine): medicines used to treat various bacterial or fungal infections.
- Procarbazine: medicine used to treat cancer.

Pregnancy and breastfeeding

Do not take DUIWELSDREKDRUPPELS if you are pregnant or breastfeeding your baby. DUIWELSDREKDRUPPELS can cause a miscarriage. The alcohol in DUIWLESDREKDRUPPELS can affect your baby and cause brain damage and growth problems in your child. A condition referred to as foetal alcohol syndrome (FAS).

During breastfeeding, DUIWELSDREKDRUPPELS can cause methaemoglobinaemia. Methaemoglobinaemia is a condition where there are abnormal amounts of methemoglobin (a protein in red blood cells) that carries and distributes oxygen in the body. This can result in an abnormally low oxygen level in the blood and can be fatal.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking DUIWELSDREKDRUPPELS.

Driving and using machines

DUIWELSDREKDRUPPELS may have an influence on your ability to drive and use machines. Since dizziness has been reported in patients taking DUIWELSDREKDRUPPELS, you should not drive or use machinery until you are sure how DUIWELSDREKDRUPPELS affects you.

It is not always possible to predict to what extent DUIWELSDREKDRUPPELS may interfere with your daily activities. You should ensure that you do not drive or use machines until you are aware of how much DUIWELSDREKDRUPPELS affects you.

DUIWELSDREKDRUPPELS contains a high percentage of alcohol.

3. How to take DUIWELSDREKDRUPPELS

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

Always take DUIWELSDREKDRUPPELS exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose in adults is:

2 ml to 4 ml (30 to 60 drops) three or four times a day (with sugar or honey if preferred).

If you take more DUIWELSDREKDRUPPELS than you should

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

If you forget to take DUIWELSDREKDRUPPELS

Do not take a double dose to make up for a forgotten individual dose.

4. Possible side effects

DUIWELSDREKDRUPPELS can have side effects.

Not all side effects reported for DUIWELSDREKDRUPPELS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DUIWELSDREKDRUPPELS, please consult your healthcare provider for advice.

If any of the following happens, stop taking DUIWELSDREKDRUPPELS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to DUIWELSDREKDRUPPELS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you experience any of the following:

- fits (convulsions)

This is a serious side effect. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- diarrhoea, flatulence, belching, stomach burning, a strong smell coming from belching/burping and your waste matter,
- headache, dizziness,
- burning during urination.

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

Reporting of side effects

If you get side effects, tell to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of DUIWELSDREKDRUPPELS.

5. How to store DUIWELSDREKDRUPPELS

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep container tightly closed.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DUIWELSDREKDRUPPELS contains

The active substance in each 5 ml DUIWELSDREKDRUPPELS is asafoetida.

The other ingredient is ethanol 62,50 % *v/v*

Sugar free

What DUIWELSDREKDRUPPELS looks like and contents of the pack

DUIWELSDREKDRUPPELS is a light brown, clear liquid with a foul odour and taste.

This product is prepared from natural ingredients and as such the colour may vary from batch to batch.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead, 2191

Hotline: 0800 122 912 (South Africa)

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B1210 (Act 101/1965)

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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