1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

DUIWELSDREKDRUPPELS 1 g per 5 ml, drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of DUIWELSDREKDRUPPELS contains 1 g asafoetida and ethanol 62,50 % *v/v.*

Sugar free

Asafoetida is extracted from Furula plants. The constituents of asafoetida are predominantly ferulic acid esters (60 %), a gum fraction (25 %), free ferulic acid (1,3 %), coumarin derivatives and volatile oils (3 % to 17 %) such as sulphur-containing compounds with disulphides as major components and various monoterpenes.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Drops.

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

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

4 CLINICAL PARTICULARS

4.1. Therapeutic indications

DUIWELSDREKDRUPPELS has been used in adults for:

- Relieving flatulence (excessive amounts of air or gas from the stomach normally causing distension.

- The treatment of dry coughs associated with bronchitis as DUIWELSDREKDRUPPELS has a useful expectorant action.

4.2. Posology and method of administration

Posology

Adults

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

Paediatric population

DUIWELSDREKDRUPPELS is contraindicated in children (see section 4.3).

Method of administration

For oral administration.

4.3. Contraindications

DUIWELSDREKDRUPPELS is contraindicated in:

- Patients hypersensitive to asafoetida, ethanol or to any of the excipients in DUIWELSDREKDRUPPELS (see section 6.1).
- Children.
- Recovering alcoholics.
- Concomitant use with disulfiram-containing preparations or products causing a disulfiram-type reaction, e.g. metronidazole.
- Porphyria.
- Pregnancy and lactation (see section 4.6).

4.4. Special warnings and precautions for use

DUIWELSDREKDRUPPELS contains a high percentage of alcohol.

Ethanol

Excessive ethanol (alcohol) intake, as in DUIWELSDREKDRUPPELS, should be avoided. Ethanol, as in DUIWELSDREKDRUPPELS, may:

- aggravate peptic ulcer disease or hepatic impairment;
- impair control of diabetes mellitus or epilepsy;
- cause a relapse and/or rekindle alcohol cravings in recovering alcoholics (see section 4.3);
- elicit a disulfiram-like response when taken concomitantly with medicines such as metronidazole (see section 4.3).

Coagulation therapy interference

Coumarins, constituents of asafoetida, as in DUIWELSDREKDRUPPELS, may interfere with anticoagulant patients on warfarin.

Porphyria

The use of alcohol, as contained in DUIWELSDREKDRUPPELS, may precipitate acute attacks of porphyria. DUIWELSDREKDRUPPELS should therefore be avoided in porphyric patients (see section 4.3).

Paediatric population

Do not give DUIWELSDREKDRUPPELS to children (see section 4.3), as it may cause methaemoglobinaemia because of the oxidising effect on haemoglobin.

4.5. Interaction with other medicines and other forms of interaction

CNS depressants

Ethanol, as in DUIWELSDREKDRUPPELS, can enhance the acute effects of central nervous system (CNS) depressants, such as hypnotics, antihistamines, opioid analgesics, antiepileptics, antidepressants, antipsychotics, and sedatives.

Modified-release opioids

'Dose dumping', a rapid and potentially fatal release of high doses of opioid from modified-release formulations may occur when some opioid medicines are taken with ethanol, as in DUIWELSDREKDRUPPELS.

Antidiabetics

Ethanol, as in DUIWELSDREKDRUPPELS, can cause hypoglycaemic reactions in diabetic patients; especially those receiving sulfonylurea antidiabetics or insulin.

Antihypertensives

Ethanol, as in DUIWELSDREKDRUPPELS:

- can cause orthostatic hypotension in patients taking medicines with a vasodilator action;
- may enhance the hypotensive effects of antihypertensives;
- when taken with verapamil increases in peak blood-alcohol concentrations of about 17 % have been reported. Such interactions may prolong or exacerbate the toxic effects of ethanol and raise its blood concentration.

Indoramin

Ethanol, as in DUIWELSDREKDRUPPELS, may increase the sedative effect of indoramin.

Analgesics

Ethanol, as in DUIWELSDREKDRUPPELS, may increase gastric bleeding caused by analgesics or NSAIDs such as aspirin or diclofenac.

Oral anticoagulants

DUIWELSDREKDRUPPELS can have an unpredictable effect on oral anticoagulants.

Vasopressin

DUIWELSDREKDRUPPELS may decrease the antidiuretic effect of vasopressin.

Other

Unpleasant or troublesome reactions, similar to those occurring with disulfiram, may occur when DUIWELSDREKDRUPPELS, which contains ethanol is taken concomitantly with chlorpropamide, griseofulvin, mepacrine, metronidazole and other nitroimidazoles, or the nitrofuran derivatives furazolidone and nifuratel, or procarbazine or some cephalosporins.

4.6. Fertility, pregnancy and lactation

DUIWELSDREKDRUPPELS is contraindicated in pregnancy and lactation (see section 4.3).

Pregnancy

Use of asafoetida, as in DUIWELSDREKDRUPPELS, is reputed to affect the menstrual cycle (emmenagogue) and to be an abortifacient (see section 4.3). Ethanol, as in DUIWELSDREKDRUPPELS, crosses the placenta and is both teratogenic and foetotoxic causing e.g. foetal alcohol syndrome (FAS). DUIWELSDREKDRUPPELS, is therefore also associated with an increased risk of miscarriage.

Breastfeeding

Asafoetida, as in DUIWELSDREKDRUPPELS, may cause toxic effects in infants (e.g. methaemoglobinaemia). Mothers breastfeeding their infants must not use DUIWELSDREKDRUPPELS (see section 4.3 and section 4.4).

Fertility

A weak sister chromatid exchange-inducing effect in mouse spermatogonia and clastogenicity in mouse spermatocytes has been documented for asafoetida, as contained in DUIWELSDREK. Chromosomal damage by asafoetida has been associated with the coumarin constituents

4.7. Effects on ability to drive and use machines

DUIWELSDREKDRUPPELS may influence the ability to drive and use machines. Adverse reactions such as dizziness have been reported.

Patients should not drive, use machinery or perform any tasks that require concentration until they are certain that DUIWELSDREKDRUPPELS does not adversely affect their ability to do so safely (see section 4.8).

Due to the alcohol content, the blood alcohol concentration may be raised and driving ability could be impaired.

4.8. Undesirable effects

a) Tabulated list of adverse reactions

System organ class	*Less frequent*	*Frequency unknown*
Blood and the lymphatic system disorders	Methaemoglobinaemia (only reported in infants)	
Immune system disorders		Hypersensitivity reactions
Nervous system disorders	Headache, dizziness, convulsion	
Gastrointestinal disorders	Odour imparted through excretions and eructation, swollen lips, gastric burning, belching, flatulence, diarrhoea	
Renal and urinary disorders	Burning during urination	
Reproductive system and breast disorders		Chromosomal damage (see section 4.6)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse reactions to:

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

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

4.9. Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).

5 PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Category and class: A 11.4.3 Medicines acting on gastrointestinal tract (other)

Pharmacotherapeutic group: Drugs for Functional Gastrointestinal Disorders.

ATC Code: A03

Mechanism of action

Asafoetida is stated to possess carminative and expectorant properties.

It has been used to treat flatulence, gas, chronic bronchitis, pertussis and cough.

5.2. Pharmacokinetic properties

Absorption

There is no data for asafoetida.

Ethanol is rapidly absorbed from the gastrointestinal tract. The rate of absorption of ethanol from the gastrointestinal tract may be modified by such factors as the presence of food and the period of time during which it is ingested.

Distribution

There is no data for asafoetida.

Ethanol is distributed throughout the body fluids.

Biotransformation

There is no data for asafoetida.

Ethanol is mainly metabolised in the liver; it is converted by alcohol dehydrogenase to acetaldehyde and is then further oxidised to acetate. A hepatic microsomal oxidising system is also involved. About 90 % to 98 % of ethanol is oxidised.

Elimination

There is no data for asafoetida.

For alcohol, the remainder is excreted unchanged by the kidneys and the lungs. It also appears in breast milk, sweat, and other secretions.

6 PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Purified water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months.

6.4. Special precautions for storage

Store at or below 25°C.

Keep container tightly closed.

6.5. Nature and contents of container

20 ml bottles.

6.6. Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

8 REGISTRATION NUMBER

B1210 (Act 101/1965)

9 DATE OF FIRST AUTHORISATION

Date of registration: Old medicine

10 DATE OF REVISION OF TEXT

03 August 2021

Die Afrikaanse Professionele Inligting is op versoek beskikbaar. Mediese Blitslyn: 0800 118 088.

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