

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

DILINCT DRY COUGH SYRUP

15 mg, syrup

Dextromethorphan hydrobromide 15 mg

Preservative: Sodium benzoate 0,20 % m/v

Contains sweeteners: 350 mg sorbitol and 9 mg saccharin sodium.

Alcohol and sugar free

Tartrazine free

Read all of this leaflet carefully before you start taking DILINCT DRY COUGH SYRUP

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

- Keep this leaflet. You may need to read it again.
- Do not share DILINCT DRY COUGH SYRUP with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

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

1. What DILINCT DRY COUGH SYRUP is and what it is used for

DILINCT DRY COUGH SYRUP is a cough syrup used to relieve a dry, non-productive cough.

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2. What you need to know before you take DILINCT DRY COUGH SYRUP

Do not take DILINCT DRY COUGH SYRUP:

- If you are hypersensitive to dextromethorphan hydrobromide or any of the other ingredients of DILINCT DRY COUGH SYRUP.
- If your child is under 5 years of age
- If you have asthma and hepatic dysfunction.
- If you are at risk of developing respiratory failure
- If you have a wet cough producing phlegm
- If you are taking anti-depressants (MAOIs) or have stopped taking these antidepressants in the last 2 weeks

Warnings and precautions

Special care should be taken with DILINCT DRY COUGH SYRUP:

- If you have a persistent respiratory condition, which occurs with smoking, asthma, emphysema (disease of the lungs), chronic bronchitis (lung inflammation) or where cough is accompanied by excessive secretions, except under the advice and supervision of a doctor. Persistent coughs should be investigated by a doctor for the possible underlying cause.
- If you have a history of drug abuse or use of psychoactive substances as it is associated with abuse and dependence.

Other medicines and DILINCT DRY COUGH SYRUP

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

- If you are taking *anti-depressants (MAOIs, fluoxetine, paroxetine, SSRI or CNS depressants: sertraline, bupropion, methadone, cinacalcet, haloperidol, perphenazine, thioridazine)*
- If you are taking *quinidine, amiodarone, flecainide, propafenone* (medicine used to treat heart rhythm disturbances)
- If you are taking *terbinafine or isavuconazole* (Antifungal medicine)

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Pregnancy, breastfeeding and fertility

Safety in pregnancy, lactation and fertility has not been established. 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 health care provider for advice before taking this medicine.

Driving and using machinery

DILINCT DRY COUGH SYRUP may lead to drowsiness and impaired concentration that may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants. It is not always possible to predict to what extent DILINCT DRY COUGH SYRUP may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DILINCT DRY COUGH SYRUP affects them.

DILINCT DRY COUGH SYRUP contains propylene glycol

DILINCT DRY COUGH SYRUP contains 50 mg propylene glycol in each 5 ml which is equivalent to 10 mg/ml. Please consult a doctor before use:

- if you child is under the age of 5,
- If you are pregnant or breastfeeding or
- If you suffer from kidney or liver disease.

DILINCT DRY COUGH SYRUP contains sorbitol

DILINCT DRY COUGH SYRUP contains 350 mg sorbitol in 5 ml which is equivalent to 70 mg/ml.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

DILINCT DRY COUGH SYRUP contains sodium benzoate

DILINCT DRY COUGH SYRUP contains 10 mg sodium benzoate in 5 ml which is equivalent to 2 mg/ml.

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Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take DILINCT DRY COUGH SYRUP

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

Always take DILINCT DRY COUGH SYRUP exactly as described in this leaflet or as your doctor, pharmacist, or nurse if you are not sure.

The usual dose:

Adults: One medicine measure (5 ml) every four hours, or two medicine measures (10 ml) every six to eight hours.

Children 5 to 12 years: Half (2,5 ml) to one medicine measure (5 ml) every six to eight hours.

Children below 5 years: Not recommended

For oral use only

Shake the bottle before use.

If you use more DILINCT DRY COUGH SYRUP than you should

In the event of an overdose, or if someone has accidentally swallowed DILINCT DRY COUGH SYRUP, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take DILINCT DRY COUGH SYRUP

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

4. Possible Side Effects

DILINCT DRY COUGH SYRUP can have side effects.

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

If any of the following happens, stop taking / using DILINCT DRY COUGH SYRUP and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

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

Tell your doctor if you notice any of the following side effects:

Less Frequent Side effects:

- swelling
- dizziness, mild drowsiness, headache, psychomotor hyperactivity
- Confusion, sleeplessness
- constipation, abdominal pain, nausea and vomiting
- Itchy rash

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, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of DILINCT DRY COUGH SYRUP. You may also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com

5. How to store DILINCT DRY COUGH SYRUP

Store all medicines out of reach of children.

Store at or below 25 °C in a well-closed container.

Do not use after the expiry date stated on the label / carton / bottle.

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 DILINCT DRY COUGH SYRUP contains

The active substance is Dextromethorphan hydrobromide 15 mg.

The preservative is Sodium benzoate 0,20 % m/v.

The other ingredients are polyvinylpyrrolidone [E1201], Acid Citric Monohydrate [E330], Saccharin Sodium [E954], Xanthan Gum [E415], Colour Raspberry Red [E30b5d], Levomenthol, Propylene Glycol [E1520], Glycerol [E422], Sorbitol 70 % [E420], Sodium benzoate [E210], Essence Raspberry and Purified water.

What DILINCT DRY COUGH SYRUP looks like and contents of the pack

DILINCT DRY COUGH SYRUP is a clear, red syrup with an odour of raspberry.

Amber glass bottles of 50 ml, 100 ml and 200 ml with a white polypropylene screw on cap.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

www.adcock.co.za

Customer Care: 0860 ADCOCK (232625)

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