

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0

DUPHALAC DRY, 10 g powder for oral solution

Contains sugar: 10 g lactose

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

DUPHALAC DRY is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use DUPHALAC DRY carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DUPHALAC DRY with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet

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

1. What DUPHALAC DRY is and what it is used for

DUPHALAC DRY oral solution sachets contain a laxative called lactulose. It makes the stool softer and easier to pass, by drawing water into the bowel. It is not absorbed into your body.

DUPHALAC DRY is used to treat the symptoms of constipation (infrequent bowel movements, hard and dry stools). DUPHALAC DRY is indicated in adults and in children and

adolescents aged 1 to 18 years.

Lactulose is used to treat portal systemic encephalopathy (a liver disease causing confusion, tremor, decreased level of consciousness).

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take DUPHALAC DRY

Do not take DUPHALAC DRY:

- if are hypersensitive (allergic) to lactulose;
- if you suffer from galactosaemia (a severe genetic disorder where you cannot digest galactose);
- if you have a blockage in your bowel (apart from normal constipation).

Warnings and precautions

Special care should be taken with DUPHALAC DRY.

Talk to your doctor or pharmacist before taking DUPHALAC DRY if you suffer from any medical conditions or illnesses, in particular:

- If you suffer from unexplained tummy ache
- If you are unable to digest milk sugar (lactose intolerant)
- If you have diabetes

If you have symptoms like excess gas in your bowels or bloating after using it, stop the treatment and consult your doctor.

Long-term use of unadjusted dosages (exceeding 2-3 soft stools per day) or misuse can lead to diarrhea and disturbance of the electrolyte balance.

High doses of DUPHALAC DRY may result in nausea and vomiting.

In these cases, your doctor will supervise the treatment carefully.

If you are an elderly patient or a patient in bad general condition and take lactulose for a

more than 6 months period, your doctor will regularly check your blood electrolytes.

During the treatment with laxatives you should drink sufficient amounts of fluids (approx. 2 litres per day, equal to 6-8 glasses).

Children

DUPHALAC DRY should not normally be given to infants and smaller children as it can disturb the normal reflexes for passing stools.

In special circumstances your doctor may prescribe DUPHALAC DRY for a child, infant or baby. In these cases your doctor will supervise the treatment carefully.

Other medicines and DUPHALAC DRY

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

Lactulose may increase the loss of potassium caused by other drugs (e.g. thiazides, steroids and amphotericin B). Use of cardiac glycosides (e.g. digoxin) along with Lactulose can increase the effect of the glycosides by decreasing potassium in the blood.

With increasing dosage a decrease of pH-value in the colon is found. Therefore drugs which are released in the colon pH-dependently (e.g. 5-ASA) can be inactivated.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think that you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before you use this medicine.

DUPHALAC DRY can be used when breastfeeding if necessary.

No effects on fertility are to be expected.

DUPHALAC DRY with food and drink

DUPHALAC DRY can be taken with or without food. There are no restrictions on what you

can eat or drink.

Driving and using machines

DUPHALAC DRY will not affect your ability to drive safely or use machines.

Important Information about some of the Ingredients of DUPHALAC DRY

DUPHALAC DRY may contain small amounts of sugars (lactose, galactose or epilactose).

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

DUPHALAC DRY may contain more than 5 g lactose/galactose/epilactose depending upon the dose taken. This should be taken into account in patients with diabetes mellitus.

15 ml of Lactulose contain 42,7 KJ (10,2 kcals) = 0,21 BU.

3. How to take DUPHALAC DRY

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

Always take DUPHALAC DRY 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.

Take your doses at the same time each day. The dose may be given once daily, for example during breakfast, or divided into two or three doses a day.

Swallow the medicine quickly. Do not keep it in your mouth.

During the treatment with laxatives you should drink sufficient amounts of fluids (approx. 2 litres per day, equal to 6-8 glasses).

It can take 1-2 days until the desired effect has been achieved since Lactulose is not degraded until it reaches the colon.

The usual dose for constipation is:

	Starting dose (3 days) gram per day	Maintenance dose gram per day
Adults	10-30 g	10-20 g
Children 7-14 years	10 g	10 g
Children 1-6 years	5-10 g	5-10 g

If there is no response within 48 hours the dosage can be increased and if diarrhea occurs dosage should be decreased.

The usual dose for Portal systemic encephalopathy is:

Starting dose 20-35 g three times a day.

If you take more DUPHALAC DRY than you should

In case of overdosage, you may experience diarrhoea and abdominal pain.

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

If you forget to take DUPHALAC DRY

If you forget to take a dose of DUPHALAC DRY, just take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking DUPHALAC DRY

The desired effect of the medicine may not be achieved.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

DUPHALAC DRY can have side effects.

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

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

- Lack of certain minerals (sodium, potassium and magnesium) in your body due to diarrhoea
- Abdominal pain
- Vomiting

These are all very serious side effects.

If you have them, you may have had a serious reaction to DUPHALAC DRY. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Flatulence (wind), especially during the first few days of treatment. This usually disappears after a couple of days.
- Nausea

Frequency unknown side effects:

- Allergic reaction (hypersensitivity).
- Rash
- Redness of the skin or mucous membranes (erythema)
- itchy skin (pruritis)
- hives, an outbreak of swollen, pale red bumps or plaques (wheals) on the skin (urticaria)

If you have any of these or any other unusual effects, and they are bad enough to trouble you, consult your doctor.

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

Reporting of side effects

If you experience side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>.

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

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5. How to store DUPHALAC DRY

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not use after the expiry date stated on the sachet and carton 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 DUPHALAC DRY contains

The active substances of DUPHALAC DRY is lactulose.

Each sachet contains 10 g lactulose.

What DUPHALAC DRY looks like and contents of the pack

DUPHALAC DRY is a white to slightly yellow coloured crystalline powder and is available in the following pack sizes:

6, 10, 20 or 30 sachets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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