

Scheduling Status:

S0

DR DU TOIT'S PAIN EXPELLER 300 mg Tablets Aspirin

Contains sugar (sucrose): 3,30 mg per tablet

DR DU TOIT'S PAIN EXPELLER is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use DR DU TOIT'S PAIN EXPELLER carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DR DU TOIT'S PAIN EXPELLER 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 10 days.

What is in this leaflet:

1. What DR DU TOIT'S PAIN EXPELLER is and what it is used for
2. What you need to know before you take DR DU TOIT'S PAIN EXPELLER
3. How to take DR DU TOIT'S PAIN EXPELLER
4. Possible side effects
5. How to store DR DU TOIT'S PAIN EXPELLER
6. Contents of the pack and other information

1. What DR DU TOIT'S PAIN EXPELLER is and what it is used for:

The active ingredient in DR DU TOIT'S PAIN EXPELLER is aspirin. It works to relieve pain of moderate intensity.

DR DU TOIT'S PAIN EXPELLER tablets are indicated for the relief of pain of moderate intensity.

2. What you need to know before you take DR DU TOIT'S PAIN EXPELLER:

Do not take DR DU TOIT'S PAIN EXPELLER:

- If you are hypersensitive (allergic) to aspirin or to any of the other ingredients in DR DU TOIT'S PAIN EXPELLER.
- If you have or have had severe heart problems.
- If you have a history of gastrointestinal bleeding associated with NSAIDs.
- If you have or have ever had a stomach ulcer, perforation or bleeding.

- If you suffer from severe kidney impairment.
- If you have a bleeding disorder.
- If you are using oral anti-coagulant medicines.
- If you are pregnant or breastfeeding your infant.
- If you are under 12 years of age (see Warnings and precautions).

Warnings and precautions:

Take special care with DR DU TOIT'S PAIN EXPELLER:

- You should not use DR DU TOIT'S PAIN EXPELLER continuously for longer than ten days without consulting your doctor.
- When given to children DR DU TOIT'S PAIN EXPELLER may cause Reye's syndrome. Reye's syndrome is a very rare disease, which can be fatal. For this reason, DR DU TOIT'S PAIN EXPELLER should not be given to children aged under 12 years, unless on the advice of a doctor (see Do not take DR DU TOIT'S PAIN EXPELLER).
- If you develop serious skin reactions, skin rash, chest tightness, wheezing or difficulty breathing, you should stop taking DR DU TOIT'S PAIN EXPELLER immediately.

Tell your doctor or pharmacist before taking DR DU TOIT'S PAIN EXPELLER if you:

- have a history of allergic reactions to NSAIDs, including attacks of asthma, swelling of your face, lips and tongue, hives, itchy skin or runny nose,
- have other allergies or asthma,
- have high blood pressure and/or suffer from heart problems. DR DU TOIT'S PAIN EXPELLER may be associated with a small increased risk of heart failure,
- are an elderly person. You may be more susceptible to the side effects of DR DU TOIT'S PAIN EXPELLER,
- have a history of inflammatory bowel disease such as ulcerative colitis or Crohn's disease (chronic inflammation and sores in the innermost lining of your colon),
- have a history of gastrointestinal diseases such as hiatus hernia, gastroesophageal reflux disease (a condition in which the stomach contents leak backwards from the stomach into the oesophagus, causing heartburn), or bleeding from the gastrointestinal tract,
- are scheduled for a surgical procedure. You must stop using DR DU TOIT'S PAIN EXPELLER several days before your surgery,
- suffer from liver or kidney problems,
- have anaemia or suffer from a deficiency of the enzyme glucose-6-phosphate dehydrogenase (G6PD),
- have diabetes,

- are dehydrated (you may feel thirsty and have a headache, dry mouth and lips).
- develop symptoms such as a high body temperature, widespread rash, swollen glands or facial swelling. This reaction can also include kidneys, liver, and heart dysfunction as well as abnormal blood test results (for example an abnormal increase in the number of disease-fighting white blood cells).

Ask your doctor if you are unsure if any of the above applies to you.

Taking DR DU TOIT'S PAIN EXPELLER while you are 20 weeks or more than 20 weeks pregnant may cause serious kidney problems in your unborn baby. This may cause a delay in your babies' lung development, as well as result in limb disabilities.

Regular use of DR DU TOIT'S PAIN EXPELLER may result in increased blood pressure in your baby's lungs. The onset of labour may be delayed and its duration increased. You should not take DR DU TOIT'S PAIN EXPELLER during pregnancy or while breastfeeding your baby.

Other medicines and DR DU TOIT'S PAIN EXPELLER:

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

It is especially important to tell your doctor if you are taking the following medicines:

- other non-steroidal anti-inflammatory drugs - NSAIDs (such as ibuprofen, naproxen, fenbufen, indomethacin and piroxicam),
- corticosteroids (to suppress the immune system),
- medicines used to prevent blood clotting such as warfarin,
- SSRIs such as sertraline or paroxetine (medicines to treat depression),
- medicines which make your urine more alkaline such as antacids,
- medicines used to treat gout such as probenecid and sulfinpyrasone,
- mifepristone (to induce abortion),
- sulphonylureas (antidiabetics),
- methotrexate (to treat some cancers, psoriasis and rheumatic disease),
- phenytoin or sodium valproate (to treat epilepsy),
- zafirlukast (to treat asthma),
- metoclopramide (to prevent sickness),
- metoprolol (to treat angina),
- acetazolamide (to treat glaucoma),

- barbiturates and other sedatives.

DR DU TOIT'S PAIN EXPELLER may interfere with some blood and urine tests. If you need to have blood and urine tests, tell your doctor you are taking DR DU TOIT'S PAIN EXPELLER.

DR DU TOIT'S PAIN EXPELLER with food or drink:

You should not drink alcohol while you are taking DR DU TOIT'S PAIN EXPELLER.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking DR DU TOIT'S PAIN EXPELLER.

You should not take DR DU TOIT'S PAIN EXPELLER during pregnancy or while you are breastfeeding your baby.

Driving and using machines:

It is not always possible to predict to what extent DR DU TOIT'S PAIN EXPELLER may interfere with the daily activities of a patient. You should be aware of how you react to DR DU TOIT'S PAIN EXPELLER before you drive or operate machinery.

DR DU TOIT'S PAIN EXPELLER contains sucrose:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this DR DU TOIT'S PAIN EXPELLER.

3. HOW TO TAKE DR DU TOIT'S PAIN EXPELLER:

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

Always take DR DU TOIT'S PAIN EXPELLER exactly as directed in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

Use the lowest effective dose for the shortest possible duration of treatment.

ADULTS: The recommended dose is one or two tablets three times a day with water.

If you take more DR DU TOIT'S PAIN EXPELLER than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre. Take this leaflet and any remaining tablets with you.

Symptoms of an overdose include ringing in the ears, spinning sensation, deafness, sweating, nausea, headache, vomiting, confusion, fast breathing rate, fever, coma and heart failure.

If you forget to take DR DU TOIT'S PAIN EXPELLER:

If you missed a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and continue to take the tablets at the usual time. Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects:

DR DU TOIT'S PAIN EXPELLER can have side effects.

Not all side effects reported for DR DU TOIT'S PAIN EXPELLER are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DR DU TOIT'S PAIN EXPELLER, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking DR DU TOIT'S PAIN EXPELLER and tell your doctor immediately or go to the casualty department of your nearest hospital:

- You have an allergic reaction. The signs may include a skin rash, swallowing or breathing problems, wheezing, worsening of asthma, swelling of your lips, face, throat or tongue.
- You get blistering, peeling, bleeding, scaling or fluid filled patches on any part of your skin. You may have a serious skin problem.
- You have a fever and yellowing of the skin or whites of the eyes, feel tired, weak or generally unwell, loss of appetite (anorexia), feeling sick (nausea), being sick (vomiting). These may be early signs of liver problems.
- Stomach ulcers or bleeding which can be severe (you may develop bloody or black tarry stools, severe stomach pain and vomit blood), stomach irritation (mild stomach pain, heartburn and feeling or being sick).
- If you develop flu-like symptoms with a high body temperature, widespread rash, swollen glands, facial swelling and abnormal blood results (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

These are all very serious side effects. If you have them, you may need urgent medical attention or hospitalisation.

Other side effects include:

- Longer bleeding time.
- Reduction of red blood cells which can make the skin pale and cause weakness or breathlessness, changes in numbers and types of blood cells seen in blood tests.
- Dizziness
- Swelling
- High blood pressure and heart failure.
- Stomach ulcers
- Bleeding from the gastrointestinal tract.
- Nausea (feeling sick), vomiting (being sick), diarrhoea.

- Indigestion, constipation, stomach pain.
- Vomiting blood or blood in your stool.
- Worsening of inflammatory bowel diseases.
- Liver problems
- Itchy skin rash caused by allergic reaction, pale or red irregular raised patches with severe itching (hives).
- Blistering, peeling, bleeding, scaling or fluid filled patches on any part of the skin.
- Runny nose
- Difficulty breathing or wheezing, worsening of asthma.

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 or 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://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf. By reporting side effects, you can help provide more information on the safety of DR DU TOIT'S PAIN EXPELLER.

5. How to store DR DU TOIT'S PAIN EXPELLER:

Store all medicines out of reach of children.

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

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

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information:**What DR DU TOIT'S PAIN EXPELLER contains:**

The active substance is aspirin.

The other ingredients are maize starch, talc and sugar and starch granules consisting of benzoic acid (preservative), gelatine powder, maize starch and sucrose.

What DR DU TOIT'S PAIN EXPELLER looks like and contents of the pack:

DR DU TOIT'S PAIN EXPELLER is a round, white scored tablet with acidic taste and odour.

DR DU TOIT'S PAIN EXPELLER is packaged in aluminium-aluminium strips or aluminium/OPA-aluminium-PVC blisters.

Strips and blisters contain 7 or 10 tablets per strip. Two or three strips are inserted together with the package insert per outer carton.

Pack sizes: 14 or 30 tablets per outer carton.

DR DU TOIT'S PAIN EXPELLER is also packaged in white opaque HDPE bottle and white polypropylene screw cap with induction seal. 10 cm of absorbent cotton and a 2 g silica gel bag are included with 1 000 tablets per bottle

Holder of Certificate of Registration:

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