PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

DOAN'S BACKACHE PILLS

Film coated tablets

Paracetamol, sodium salicylate, buchu powder extract

Sugar free

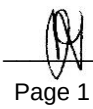
Read all of this leaflet carefully because it contains important information for you

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

- Keep this leaflet. You may need to read it again.
- Do not share DOAN'S BACKACHE PILLS 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 10 days.

What is in this leaflet

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

Signed: 

1. What DOAN'S BACKACHE PILLS is and what it is used for

DOAN'S BACKACHE PILLS contains paracetamol and sodium salicylate which belongs to a group of medicines called analgesics, which relieve pain and reduce fever and inflammation. Buchu powder extract has anti-inflammatory properties.

DOAN'S BACKACHE PILLS is used for the treatment of pain and inflammation in the muscles, joints and/or back.

2. What you need to know before you take DOAN'S BACKACHE PILLS

Do not take DOAN'S BACKACHE PILLS:

- if you are hypersensitive (allergic) to paracetamol, sodium salicylate, buchu powder extract or any of the other ingredients of DOAN'S BACKACHE PILLS (listed in section 6)
- if you have liver or kidney problems.

Warnings and precautions

Take special care with DOAN'S BACKACHE PILLS

- if you have liver problems
- if you have kidney problems
- if you must go for an operation, you should stop taking DOAN'S BACKACHE PILLS a few days before your operation
- safety and efficacy of DOAN'S BACKACHE PILLS in children younger than 12 years have not been established, its use is therefore not recommended.

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Other medicines and DOAN'S BACKACHE PILLS

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

The following medicines are particularly important:

- metoclopramide (used to treat nausea (feeling sick) and vomiting (being sick)
- probenecid (used to treat gout)
- colestyramine (used to lower high levels of cholesterol in your blood)
- aspirin (used to treat pain and fever).

DOAN'S BACKACHE PILLS with food and drink

You should take DOAN'S BACKACHE PILLS after a meal with enough fluid (preferably water).

Pregnancy and breastfeeding

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 DOAN'S BACKACHE PILLS.

Driving and using machines

No studies on the effects on the ability to drive a vehicle and use machines have been performed. However, DOAN'S BACKACHE PILLS has no effect on your ability to drive or use machines (see section 4).

3. How to take DOAN'S BACKACHE PILLS

Do not share your medicines with any other person. Always take DOAN'S BACKACHE PILLS exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

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Adults and children (12 years and older):

DO NOT TAKE MORE THAN THE USUAL DOSE.

The usual dose is two (2) tablets four (4) times a day after a meal. The dose can be increased to three (3) tablets four (4) times a day if necessary, to manage your pain.

Taken DOAN'S BACKACHE PILLS with enough fluid (preferably water). To ease swallowing, tablets may be broken in parts or crushed before being swallowed with fluid.

You should not use DOAN'S BACKACHE PILLS for more than 10 days unless advised by a health care provider.

If you take more DOAN'S BACKACHE PILLS than you should

Symptoms of paracetamol (one of the active ingredients in DOAN'S BACKACHE PILLS) overdosage in the first 24 hours include nausea, vomiting, loss of appetite and stomach 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 DOAN'S BACKACHE PILLS

If you forget to take a dose, take it as soon as you remember.

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

4. Possible side effects

DOAN'S BACKACHE PILLS can have side effects.

Not all side effects reported for DOAN'S BACKACHE PILLS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DOAN'S BACKACHE PILLS, please consult your doctor, pharmacist or other health care provider for advice.

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If any of the following happens, stop taking DOAN'S BACKACHE PILLS 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 DOAN'S BACKACHE PILLS. You may need urgent medical attention or hospitalisation.

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

- bleeding or bruising more easily than normal
- signs of recurrent infections such as fever or a sore throat
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems
- painful, blistering or peeling skin rash
- swollen, red skin with small white pus filled spots.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- nausea
- vomiting
- indigestion.

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

Signed: _____

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to the South African Health Products Regulatory Authority (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 DOAN'S BACKACHE PILLS.

You may also report side effects directly to Mentholatum SA at https://www.mentholatum.co.za.

5. How to store DOAN'S BACKACHE PILLS

- Store at or below 25 °C.
- Protect from light and moisture.
- Keep the tablets in the original container until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DOAN'S BACKACHE PILLS contains:

The active substances per film coated tablet are 97,19 mg paracetamol, 48,59 mg sodium salicylate and 32,40 mg buchu powder extract.

The other ingredients are acid hydrolysed starch (1500), Flexicoat Grey (containing polyethylene glycol, polyvinyl alcohol, Sicovit Black (E172), Sicovit Red (E172), Sicovit Yellow (E172), talcum, titanium dioxide (E171), magnesium stearate, povidone, stearic acid and talcum.

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What DOAN'S BACKACHE PILLS looks like and contents of the pack:

Brownish-grey, film coated tablets.

White, PP securitainer with white, LDPE securitainer closure with an orange and black label printed on the securitainer. Each securitainer contains 18, 48 or 100 tablets.

Polypaper sachet (printed) containing 2 tablets, packed on a printed cardboard carton. Each cardboard carton contains 48 sachets.

Holder of Certificate of Registration:

Mentholatum SA (Pty) Ltd

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Steenberg Office Park

Silverwood Close

Tokai 7945

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This leaflet was last revised in

Application number

B 957 (Act 101 of 1965)

Access to the corresponding Professional Information

The professional information is available electronically on Mentholatum SA's website:

https://www.mentholatum.co.za/product-information

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