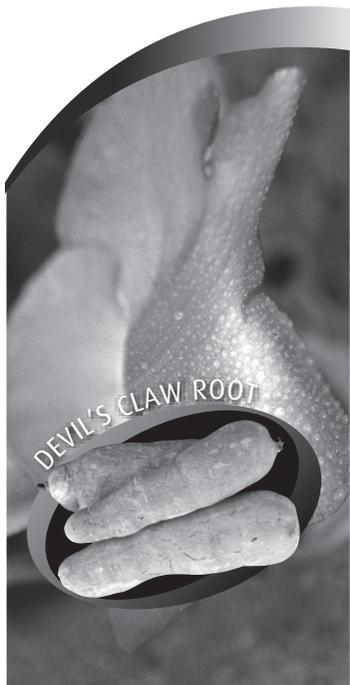




Package Leaflet:
Information for the user



Atrosan[®]
Devil's Claw
film-coated tablets



Information

Read all of this leaflet carefully before you start taking this product because it contains important information for you.

Always take this product exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 4 weeks.

What is in this leaflet

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

1. What Atrosan is and what it is used for

Atrosan is a traditional herbal medicinal product containing the extract of Devil's Claw root.

It is used to relieve:

- Minor joint pain

This is exclusively based on long-standing use.

Atrosan is for use in adults.

Do's and Don'ts for taking Atrosan

2. What you need to know before you take Atrosan

Do not take Atrosan

- If you are allergic to:
 - Devil's Claw (also known as Harpagophytum). This product contains Devil's Claw root.
 - Any of the other ingredients of this product (listed in section 6).
- If you have an ulcer (either a gastric and/or duodenal ulcer).
- If you are under 18 years of age.
- If you are pregnant or breast-feeding.

Warnings and precautions

- Talk to your doctor **before** taking this product if you have heart problems.
- Talk to your doctor or pharmacist if:
 - Your symptoms worsen, persist or if new symptoms develop.
 - You do not feel any benefit from this product within 4 weeks.

- Your joint pain is accompanied by swelling of the joint, redness or a fever.

Children and adolescents

- Do not give this product to children or adolescents under 18 years of age.

Other medicines and Atrosan

- You can take this product with other medicines.
- If you are speaking to your doctor, pharmacist or nurse always remember to tell them about any medicines you are taking, including herbal remedies such as Atrosan.

Pregnancy and breast-feeding

- Do not take this product if you are pregnant or breast-feeding.

Driving and using machines

- In rare cases this product may cause dizziness and drowsiness. If this happens to you, do not drive or use machines.

Atrosan contains lactose

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

Using

3. How to take Atrosan

Always take this product 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.

Recommended dose

Adults and older people: Take 1 tablet twice daily immediately after food. The dose can be increased to 2 tablets twice daily if relief is not obtained after 3 to 5 days.

For oral short-term use only. Do not take more than the recommended dose.

If you take more Atrosan than you should

- If you take too much and feel ill, talk to your doctor.

If you forget to take Atrosan

- Do not worry about a missed dose. Take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

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



Side effects

4. Possible side effects

Like all products, this product can cause side effects, although not everybody gets them.

Minor side effects

Digestive symptoms

- Stomach discomfort
- Feeling sick
- Digestive upsets such as sickness or diarrhoea

Other side effects

- Rash
- Itching
- Headache
- Dizziness

Stop taking this product if you find these are troubling you. Talk to your doctor, pharmacist or nurse if you are concerned.

These side effects are rare and likely to affect less than 1 in every 1,000 people.

Reporting of side effects

- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

- You can also report side effects directly via:

IMB Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
E-mail:
imbpharmacovigilance@imb.ie

- By reporting side effects you can help provide more information on the safety of this medicine.



Information

5. How to store Atrosan

- Keep this product out of the sight and reach of children.
- Do not use this product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
- This product does not require any special storage conditions.
- Do not use this product if you notice a change in appearance. The tablets should be white in colour.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Atrosan contains

Each film-coated tablet contains 480 mg of extract (as dry extract) from Devil's Claw root (*Harpagophytum procumbens* D.C. and/or *H. zeyheri* L. Decne.) (1.5-3.0:1). Extraction solvent: Ethanol 60% V/V.

The other ingredients used for the tablet are lactose monohydrate, maize starch, microcrystalline cellulose, precipitated silica, anhydrous colloidal silica and magnesium stearate (vegetable source).

The tablet coating contains talc, titanium dioxide, macrogol and hypromellose.

What Atrosan looks like and contents of the pack

Atrosan tablets are oval-shaped and white in colour. Atrosan is available in packs containing 30, 50, 60 and 120 tablets. Not all pack sizes may be marketed.

Traditional Herbal Registration Holder and Manufacturer

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What is Devil's Claw?

Devil's Claw is a plant which is native to southern Africa. It produces storage tubers (roots) and it is the extract of these tubers which is used to make this product.

You should also know

Bioforce runs a helpline by phone and email which can provide you with further information.

E-mail: enquiries@avogel.co.uk
Phone: **1 890 930 070**

You can get a larger print or audio version of this leaflet.

Call this number:
1 890 930 070

