

Macrogol 4000 tanilas[®] 10g

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- You must consult your doctor if your symptoms worsen or do not improve.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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

1. WHAT TANILAS IS AND WHAT IT IS USED FOR

Tanilas contains the active substance Macrogol 4000 and belongs to a group of medicines called osmotic laxatives. It works by adding water to the stools, which helps to overcome problems caused by very slow bowel movements. Tanilas is not absorbed into the bloodstream or broken down in the body.

Tanilas is used for the treatment of constipation in adults and children aged 8 years and above.

This medicine is a powder that you dissolve in a glass of water (at least 50ml) and drink. It usually takes 24 to 48 hours to work. The treatment of constipation with any medicine should only be in addition to a healthy lifestyle and diet.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TANILAS

Do not take Tanilas:

- if you are allergic (hypersensitive) to macrogol (polyethylene glycol) or any of the other ingredients of this medicine (listed in section 6).
- if you have an existing disease, such as, severe intestinal disease:
 - inflammatory bowel disease (such as ulcerative colitis, Crohn's disease, abnormal dilation of the bowel)
 - perforation of the bowel or risk of perforation of the bowel
 - ileus or suspicion of intestinal obstruction
 - painful abdominal syndromes of uncertain cause

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your pharmacist or doctor before taking the medicine.

Warnings and Precautions

Cases of allergic reactions involving rash and swelling of the face or throat (angioedema) have been reported in adults after taking products containing macrogol (polyethylene glycol). Isolated severe allergic reactions have been reported causing faintness, collapse or breathing difficulties and feeling generally unwell.

If you experience any of these symptoms you should stop taking Tanilas and seek medical help immediately.

As this medicine can sometimes cause diarrhoea, check with a doctor or pharmacist before taking this medicine if you:

- have impaired liver or kidney function,
- are taking diuretics (water tablets) or are elderly as you may be at risk of low sodium (salt) or potassium levels in the blood.

Other medicines and Tanilas

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast feeding

Tanilas can be used during pregnancy and breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Not relevant

Important information about some of the ingredients of Tanilas

If you have been told by your doctor that you have an intolerance to some sugars (sorbitol), contact your doctor before taking this medicine. This medicine contains a small amount of a sugar called sorbitol, which is converted to fructose. Due to the presence of sulphur dioxide, it may rarely cause severe hypersensitivity reactions and breathing difficulties. Tanilas can, however, be used if you are diabetic or on a galactose-free diet.

3. HOW TO TAKE TANILAS

Always take Tanilas exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children over 8 years

The recommended dose is one to two sachets per day, preferably taken as a single dose in the morning.

The daily dose can be adjusted according to the effect obtained and may range from one sachet every other day (especially in children) to up to a maximum of two sachets per day.

Dissolve the contents of the sachets in a glass of water (at least 50 ml) immediately before use and drink the liquid.

Please note:

- Tanilas usually takes 24 to 48 hours to work.
- In children, the duration of treatment with Tanilas should not exceed 3 months.
- Improvement in the frequency of your bowel movements after taking Tanilas can be maintained by keeping to a healthy lifestyle and diet.
- Talk to your pharmacist or doctor if the symptoms worsen or do not improve.

If you take more Tanilas than you should

Taking too much Tanilas may cause diarrhoea, stomach pains or vomiting. The diarrhoea usually disappears when treatment is stopped or the dose reduced.

Package leaflet: Information for the patient

10 g, powder for oral solution in sachet

If you suffer from severe diarrhoea or vomiting you should contact a doctor as soon as possible as you may require treatment to prevent loss of salts (electrolytes) from fluid loss.

If you forget to take Tanilas

Take the next dose as soon as you remember but do not take a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tanilas can cause side effects, although not everybody gets them.

The side effects that are usually mild and do not last long include:

In children:

Common (may affect up to 1 in 10 people)

- Abdominal (belly) pain
- Diarrhoea which may also cause soreness around the back passage (anus).

Uncommon (may affect up to 1 in 100 people)

- Nausea (feeling sick) or vomiting
- Abdominal (belly) bloating

Not known (frequency cannot be estimated from available data)

- Allergic (hypersensitive) reactions (rash, hives (urticaria), swelling of the face or throat, breathing difficulties, faintness or collapse)

In adults:

Common (may affect up to 1 in 10 people)

- Abdominal (belly) pain
- Abdominal (belly) bloating
- Nausea (feeling sick)

Uncommon (may affect up to 1 in 100 people)

- Vomiting
- Urgent need to go to the toilet
- Faecal incontinence

Not known (frequency cannot be estimated from available data)

- Low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm
- Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma
- Dehydration caused by severe diarrhoea especially in the elderly
- Symptoms of an allergic reaction such as skin redness, rash, hives (urticaria), swelling of the face or throat, breathing difficulties, faintness or collapse

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

Greece: National Agency for Medicines (Mesogeion 284, 15562 Chologos, Athens, Tel: +30 21 32040380/337, Fax: +30 21 06549585, Website: <http://www.eof.gr>).

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

5. HOW TO STORE TANILAS

Keep this medicine out of the sight and reach of children.

Do not take Tanilas after the expiry date which is stated on the base of the carton. The expiry date refers to the last day of that month.

Tanilas does not require any special storage conditions.

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 Tanilas contains

The active substance in each sachet is 10 grams of macrogol 4000.

The other ingredients are:

Saccharin sodium (E 954) and orange-grapefruit flavour which contains orange and grapefruit oils, concentrated orange juice, citral, acetaldehyde, linalol, ethyl butyrate, alpha terpineol, octanal, beta and gamma hexenol, maltodextrin, gum arabic, sorbitol (E 420), BHA (E 320) and sulphur dioxide (E 220).

What Tanilas looks like and contents of the pack

Tanilas is an almost white powder that smells and tastes of orange-grapefruit, for making up into a drink.

Tanilas is available in packs of 10, 20, 50 and 100 sachets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

Beaufour Ipsen Industrie, Rue Ethe Virtron, 28100 Dreux, France

Promotion-Distribution

Arriani Pharmaceuticals S.A, 85 Lavriou Ave., 190 02 Peania, Athens Greece, Tel: +30 210 6683000, Fax: +30 2106683250

This medicinal product is authorised in the Member States of the EEA under the following names:

Forax 10g in Austria, Belgium, Czech Republic, Estonia, France, Latvia, Lithuania, Luxembourg, Poland, Portugal, Slovakia and The Netherlands.

Dulcolax M Balance in Germany. Tanilas 10g in Greece, Idrolax in Ireland, Paxabel 10g in Italy and Dulcolabalance in the United Kingdom,

This leaflet was last revised in 16/07/2015