Package Leaflet: Information for the user

Digestisan

oral drops

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 a week.

What is in this leaflet

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

1. What Digestisan is and what it is used for

Digestisan is a traditional herbal medicinal product containing the tinctures of fresh Artichoke leaves, fresh Dandelion root and herb, Boldo leaves and fresh Peppermint herb.

Digestisan is used to relieve digestive discomfort. This is exclusively based on long-standing use.

Used to relieve:

- Indiaestion
- Feelings of fullness
- Flatulence

Digestisan is for use in adults.

2. What you need to know before you take Digestisan

Do not take Digestisan

- If you are allergic to:
 - o Any of the ingredients of this product (listed in section 6)
 - Plants of the daisy (Asteraceae/Compositae) family. Artichoke and Dandelion are members of the daisy family.
 - Menthol
- If you **suffer** from:
 - o Blockage of the bile duct
 - o Inflammation of the bile ducts (cholangitis)
 - Gallstones
 - Biliary disorders
 - Liver disease
- If you are pregnant, may become pregnant or if you are breastfeeding.

Warnings and precautions

- Talk to your doctor before taking this product if you suffer from:
 - Kidney failure
 - Diabetes
 - Heart failure
- If you suffer from heartburn the Peppermint in this product may make it worse.
- Talk to your doctor or pharmacist if your symptoms worsen or do not improve within a week.

Children and adolescents

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

Other medicines and Digestisan

- Do not take this product if you are already taking another medicine which is affected by alcohol.
- 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 Digestisan.

Pregnancy and breast-feeding

• Do not take this product if you are pregnant, may become pregnant or if you are breast-feeding.

Driving and using machines

This product contains alcohol (see below for alcohol content). Overdose
of this product may result in alcohol intoxication.

Digestisan contains alcohol

- This medicine contains 255 mg of alcohol (ethanol) in each 20 drop dose, equivalent to 484.5 mg/ml.
- The amount in each dose (20 drops) of this medicine is equivalent to less than 7 ml beer or 3 ml wine.
- The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take Digestisan

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 (18 years and over): Take 15-20 drops in a little water three times daily.

Not for use in children or those under 18.

For oral short-term use only.

Do not take more than the recommended dose.

If you take more Digestisan than you should

- If you take too much of this product talk to your doctor.
- Overdose of this product may result in alcohol intoxication.

If you forget to take Digestisan

- Do not worry about the 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.

4. Possible Side Effects

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

Side effects

Digestive symptoms

• Stomach pain

- Digestive upset
- Excessive acid
- Worsening of gastric reflux and heartburn

These are often short-lived and should go away by themselves. However if they are troubling you, talk to your doctor or pharmacist.

Other

• Allergic reactions

Stop taking the product if these occur.

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 HPRA Pharmacovigilance. Website: www.hpra.ie
- By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Digestisan

- 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. It should be a clear liquid that is brown 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 Digestisan contains

One dose (20 drops) of oral liquid contains the tinctures of:

Fresh Artichoke leaves 218 mg

(Cynara scolymus L.) (1:30-31)
Extraction solvent: Ethanol 65% V/V
Fresh Dandelion root & herb 218 mg
(Taraxacum officinalis WEB.) (1:17-18)
Extraction solvent: Ethanol 51% V/V

Boldo leaves 34 mg

(Peumus boldus MOLINA.) (1:10-11) Extraction solvent: Ethanol 70% V/V Fresh Peppermint herb 15 mg

(Mentha x piperita L.) (1:18-19) Extraction solvent: Ethanol 65% V/V

1 ml of Digestisan oral drops is equivalent to 38 drops.

The other ingredients used for the liquid are ethanol and water.

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What Digestisan looks like and contents of the pack

Digestisan is a clear liquid that is brown in colour. Digestisan is available in 15 ml, 30 ml, and 50 ml bottles. Not all pack sizes may be marketed.

About the ingredients of Digestisan

• Artichoke and Dandelion are flowering plants which have been used as food throughout the world for many years.

- Boldo is an evergreen shrub which is native to South America. The extract of the leaves is used to make this product.
- Peppermint is a herb native to Europe which has been consumed as a food and medicine for many years.

You should also know

A. Vogel Ireland runs a helpline by phone and e-mail which can provide you with further information.

E-mail: enquiries@avogel.ie

Phone: 0818 930 070

You can get a larger print or audio version of this leaflet. Call this number: 0818 930 070