# INSERT TEXT FOR PRODUCT AUTHORIZED UNDER MDD

# Tasectan®

**Intended use**

Tasectan is a medical device used to restore the physiological function of the intestinal walls. It is specifically formulated to control and reduce the symptoms associated with diarrhoea resulting from various causes, such as abdominal tension and frequent defecation. It is effective within 12 hours.

The Gelatin Tannate of which the product is composed is not altered in the stomach and acts by forming a film which protects the intestinal mucosa, reducing the frequency and duration of diarrhoea episodes.

**Presentations**

Twenty or ten sachets containing powder for paediatric use.

Blister pack containing fifteen or eight capsules for adult use.

**Composition**

Powder: 250 mg Gelatin Tannate (Porcine origin).

Capsules: 500 mg Gelatin Tannate (Porcine origin), Corn Starch and Magnesium Stearate (Vegetable origin).

**Instructions for use**

Powder: the content of one sachet must be mixed with a small quantity of a not hot drink such as milk, fruit juices or water and administered immediately. It can also be added to yoghurt or any other food. Do not administer the product directly without mixing it.

Capsules: Swallow the capsule with liquids.

**Dosage**

Children under 3 years: 1 sachet every 6 hours until symptoms disappear.

Children aged 3 to14 years: 1 or 2 sachets every 6 hours until symptoms disappear.

Adults and children older than 14 years: 1-2 capsules every 4-6 hours until symptoms disappear.

**Warnings**

- Consultation with a healthcare professional before using the product is not necessary. However, such consultation is advisable in case of severe or persistent symptoms or when there are doubts on the diagnosis.
- In the case of diarrhoea in children below 3 years and elderly people, consultation with a healthcare professional is recommended, especially when other symptoms are present.
- This medical device is not a pharmacological treatment. If such treatment is recommended by a healthcare professional, the device can be administered concomitantly.
- An abundant intake of liquid and dietary measures accepted in the management of diarrhoea is recommended.
- Even though no side effects are known, it is recommended that the product is not used during pregnancy or breastfeeding, unless otherwise indicated by a healthcare professional.
- Do not use the product after the expiry date printed on the package.
- Do not use the product if the blister or sachets are opened or damaged.
- This medical device does not require special storage conditions. Do not freeze.
- Keep product out of reach of children.

**Contraindications**

Tasectan must not be used in patients with known hypersensitivity to Gelatin Tannate or any other ingredient of the product.

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# Tasectan®

**Description**

Tasectan is a substance-based medical device based on gelatin tannate, a complex resulting from combining tannic acid and gelatine. Gelatin tannate is not altered in the stomach and acts by forming a protective film on the intestinal mucosa that prevents the contact and adherence of pathogens and related toxins associated with diarrhoeal disorders, thus favouring the restoration of altered intestinal function and therefore, reducing the frequency and duration of diarrhoea episodes.

**Intended use**

Tasectan is intended to restore the physiological functions of the intestinal walls. It is specifically formulated for the reduction and control of symptoms related to diarrhoeal episodes of different aetiologies, such as frequent liquid or soft stools and abdominal discomfort. It is effective within 12 hours.

**Presentation**

Box containing 10 or 20 sachets with powder for children and/or adults use.

Blister pack containing 8, 15 or 45 capsules for adults and children older than 14 years use.

Not all presentations might be available.

**Composition**

Each sachet contains: 250 mg gelatin tannate.

Each capsule contains: 500 mg gelatin tannate and other components including corn starch and magnesium stearate (vegetable origin).

The capsules are composed by hypromellose, titanium dioxide, and, as colorants, quinoline yellow and erythrosine – FD&C Red 3 (the following technological additives could also be present, caranauba wax, carrageenan, potassium chloride)

**Instructions for use**

Powder: The content of one sachet must be mixed with a small quantity of a not hot drink such as milk, fruit juices or water and administered immediately. It can also be added to yoghurt or any other food. Do not administer the product directly without mixing it.

Capsules: Swallow the capsule with liquids.

**Dosage**

Tasectan is intended to be used in children and adults.

- Children under 3 years: 1 sachet every 6 hours.
- Children aged 3 to 14 years: 1 or 2 sachets every 6 hours.
- Adults and children older than 14 years: 1-2 capsules or 2-4 sachets every 4-6 hours.

Maintain treatment 24 hours after resolution of symptoms.

**Warnings and Precautions**

- In general, consultation with a healthcare professional before using the medical device is not necessary. However, it is advisable in the following cases: children below 3 years and elderly people, in the presence of severe and persistent symptoms; or when there are doubts about the diagnosis.
- This medical device is not a pharmacological treatment. It can be administered concomitantly with another treatment prescribed by a healthcare professional if needed.
- Abundant intake of liquid and dietary measures accepted in the management of diarrhoea is recommended.
- The safety and efficacy of Tasectan has not yet been stablished in pregnant women or during breastfeeding period. Therefore, the use of Tasectan in this patient groups should be performed under the supervision of a healthcare professional.
- Do not use the medical device after the expiry date printed on the package.
- Do not use the medical device if the blister or sachets are opened or damaged.
- This medical device does not require special storage conditions. Do not freeze.
- Keep this medical device out of sight and reach of children.

- Any serious incident that has occurred using the medical device should be reported to the manufacturer and the local competent authority.

**Contraindications**

Tasectan must not be used in patients with known hypersensitivity to any component listed in the composition of the **product.**

**Side effects**

No relevant side effects related to the use of Tasectan have been reported in clinical studies.

A summary of safety and clinical performance is available in the manufacturer website (www.noventure.com) and in the European database on medical devices (Eudamed - https://ec.europa.eu/tools/eudamed), where it is linked to the Basic UDI-DI of Tasectan Capsules (843659383TAS123LX) and with the Basic UDI-DI of Tasectan Sachets (843659383TAS133M2).

**Interactions**

It is recommended administering Tasectan at least two hours after any other oral treatment to avoid interactions. Specifically, Tasectan may affect the absorption of iron.

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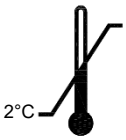
**Meaning of the symbols used**

- Primary packaging:

| SYMBOL | TITLE | DESCRIPTION OF SYMBOL |
|---|---|---|
|  | Manufacturer | Indicates the medical device manufacturer, as defined in Medical Device Regulation 2017/745. |
|  | Use-by date | Indicates the date after which the medical device is not to be used. |
|   | Batch code | Indicates the manufacturer's batch code so that the batch or lot can be identified. |
|  | Consult leaflet | Indicates the need for the user to consult the leaflet. |

- Secondary packaging:

| SYMBOL | TITLE | DESCRIPTION OF SYMBOL |
|---|---|---|
|  | Manufacturer | Indicates the medical device manufacturer, as defined in Medical Device Regulation 2017/745. |
|  | Use-by date | Indicates the date after which the medical device is not to be used. |
|  | Batch code | Indicates the manufacturer's batch code so that the batch or lot can be identified. |
|  | Consult leaflet | Indicates the need for the user to consult the leaflet. |
|  | Temperature limit | Indicates the temperature limits to which the medical device can be safely exposed, in this special case no lower than 2°C. |
|  | Catalogue number | Indicates the manufacturer's catalogue number so that the medical device can be identified. |
|  | Medical device | Indicates that the product is a medical device. |
|  | Unique device identifier | Indicates carrier that contains unique device identifier information |
|  | Contains biological material of animal origin | Indicates a medical device that contains biological tissue, cells, or their derivatives, of animal origin. |