Unofficial translation of the German package leaflet

Package leaflet: Information for the user

Tannacomp®

500 mg/50 mg film-coated tablets

Active substances: Albumin tannate / ethacridine lactate monohydrate

For use in adults, adolescents, and children over 5 years.

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist 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 or pharmacist. 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 3-4 days.

What is in this leaflet

1. What Tannacomp® is and what it is used for

Tannacomp® is a medicine to treat gastrointestinal problems (anti-diarrhoeal drug).

Intended uses

- Treatment of acute non-specific diarrhoea
- Prevention and treatment of traveller's diarrhoea

Note:

In the event of severe diarrhoea, especially if accompanied by fever and/or bloody stools, please seek medical assistance, because specific treatment may be required.

2. What you need to know before you take Tannacomp®

Do not take Tannacomp® :

- if you are allergic to albumin tannate (contains chicken egg protein), ethacridine lactate monohydrate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Tannacomp® .

Other medicines and Tannacomp®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Products containing iron should not be taken at the same time as Tannacomp® , but instead should be taken after an interval of several hours, otherwise the effect of the iron preparation may be reduced.

Tannacomp® with food and drink

The effect of Tannacomp® is affected by diet. In addition to ensuring adequate fluid intake, as already mentioned, high-fibre foods and spicy foods especially should be avoided.

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.

Tannacomp® should only be used following specific instruction from a doctor during pregnancy, especially in the first three months, and during breast-feeding.

3. How to take Tannacomp®

Always take this medicine 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.

The dose and frequency depend on the severity of the diarrhoea.

Unless prescribed differently by a doctor, the standard dose is:

Children aged 5-14 years:	1 film-coated tablet 3 to 4 times daily
Adults:	1-2 film-coated tablets 4 times daily
As preventative treatment in adults:	1 film-coated tablet twice daily

The film-coated tablets should be taken with sufficient fluids before or with meals. If necessary, the film-coated tablets can also be crushed and mixed with food or drinks.

In children and the elderly, diarrhoea can rapidly lead to a dangerous loss of fluids and electrolytes, particularly if accompanied by vomiting. Therefore, it is necessary to pay special attention to adequate replacement of water and electrolytes.

Tannacomp® should be taken regularly until the diarrhoea has resolved.

Do not take Tannacomp® for longer than 3-4 days without medical advice.

If you take more Tannacomp® than you should

Tannacomp® does not lead to constipation, even in the event of overdose. Serious health problems as a result of overdose are not known.

If you forget to take Tannacomp®

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

If you stop taking Tannacomp®

This may result in a return of the symptoms.

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

4. Possible side effects

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

The frequency data for side effects is based on the following categories:

- Very common: more than 1 in 10 patients treated
- Common: between 1 and 10 patients treated per 100
- Uncommon: between 1 and 10 patients treated per 1,000
- Rare: between 1 and 10 patients treated per 10,000
- Very rare: fewer than 1 in 10,000 patients treated
- Unknown: frequency cannot be estimated from the available data

Possible side effects

Immune system disorders
Rare

In rare cases, allergic reactions (hypersensitivity reactions) to albumin tannate and ethacridine lactate monohydrate have been observed.

Gastrointestinal tract,
Note:

The bowel contents may develop a yellowish colour after taking Tannacomp® due to the ethacridine lactate monohydrate content.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Germany:
Bundesinstitut für Arzneimittel und Medizinprodukte
[Federal Institute for Drugs and Medical Devices]
Abt. Pharmakovigilanz
[Department of Pharmacovigilance]
Kurt-Georg-Kiesinger Allee 3
D-53175 Bonn
Website: http://www.bfarm.de

Luxembourg:
Direction de la Santé – Division de la Pharmacie et des Médicaments
[Health Department - Unit for Pharmacy Services and Medicinal Products]
Villa Louvigny – Allée Marconi
L-2120 Luxembourg
Website: http://www.ms.public.lu/fr/activites/pharmacie-medicament/index.html

5. How to store Tannacomp®

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

Do not use this medicine after the expiry date which is stated on the blister pack and carton after "Expiry date". The expiry date refers to the last day of that month.

Storage conditions

Do not store above 30°C.

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 Tannacomp® contains

The active substances are:

1 film-coated tablet contains:

Albumin tannate	500 mg
Ethacridine lactate monohydrate	50 mg

The other ingredients are:

Microcrystalline cellulose (Ph. Eur.), sodium starch glycolate (type A) (Ph. Eur.), colloidal silicon dioxide, talc (Ph. Eur.), magnesium stearate [plant-based] (Ph. Eur.), poly(vinyl alcohol), macrogol 3350, titanium dioxide, hydrated iron (III) oxide-hydroxide, iron (III) oxide

What Tannacomp® looks like and contents of the pack

Orange-brown, oblong film-coated tablets, scored on both sides.

Original packs with 20 film-coated tablets and 50 film-coated tablets.

Pharmaceutical company and manufacturer

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