

## PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

### **Tavipec - capsules** Active substance: Spike oil

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have 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.
- Talk to a doctor if you do not feel better or even worse after 7 days.

#### **What is in this leaflet:**

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

### **1. WHAT TAVIPEC IS AND WHAT IT IS USED FOR**

*Tavipec* is an herbal medicine for the treatment of the symptoms of acute bronchitis and for the supportive treatment of rhinosinusitis or cough associated with the common cold.

*Tavipec* - capsules are used in adults and adolescents age 12 and above.

Talk to a doctor if a high fever occurs or if you do not feel better or even worse after 7 days.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TAVIPEC**

**Do not take *Tavipec*,** if you are allergic to spike oil or any of the other ingredients of this medicine listed in section 6.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking *Tavipec*.

In case of dyspnoea, fever, as well as in suppurative or bloody ejection, a doctor should be called immediately.

#### **Children:**

As there is not enough data available, the use in children below the age of 12 years cannot be recommended.

#### **Other medicines and *Tavipec***

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

No interaction studies have been conducted.

### **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 the pharmacist before taking this medicine.

As no sufficient data are available, taking this medicine during pregnancy and breast-feeding cannot be recommended.

### **Driving and using machines**

No studies have been conducted on the ability to drive or use machines.

**Tavipec - capsules contain sunset yellow (E 110)** which can cause allergic reactions.

## **3. HOW TO TAKE TAVIPEC CAPSULES**

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

The recommended dose is:

*Adults and adolescents age 12 and above: 2 capsules 3 times a day.*

### How to take Tavipec capsules:

Take half an hour before meals without chewing with plenty of fluids.

### Duration of treatment:

Talk to a doctor if a high fever occurs or if you do not feel better or even worse after 7 days.

### Paediatric population:

As there is not enough data available, the use in children below the age of 12 years cannot be recommended.

### **If you take more Tavipec than you should**

There are no reported cases of overdoses.

### **If you forget to take Tavipec**

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 or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

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

Side effects may occur:

uncommon	affects more than 1 in 1,000 but less than 1 in 100 patients.
very rare	affects less than 1 in 10,000 patients

Uncommon: belching and mild nausea may occur.  
Very rare: hypersensitivity reactions of the skin have been observed.

### **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 to the

Federal Office for Safety in Health Care Inst.

Pharmacovigilance

Traisengasse 5

AT-1200

VIENNA

Fax: + 43 (0) 50 555 36207

Website: <http://www.basg.gv.at/>

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

## **5. HOW TO STORE TAVIPEC**

Keep the coated tablets in the outer carton in order to protect from light. Store below 30°C

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 carton after <<EXP:>>. The expiry date refers to the last day of that month.

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 FURTHER INFORMATION**

### **What *Tavipec* contains**

- The active substance is spike oil (*Spicae Aetheroleum*)
- The other ingredients are:
- *Capsule*: Gelatine, glycerol 85 %, quinoline yellow (E-104), yellow-orange (E-110),
- *Capsule coating*: Methacrylic acid-ethyl acrylate-copolymer, sodium dodecyl sulfate, propylene glycol, polysorbate 80, glycerol monostearate.

### **What *Tavipec* looks like and contents of the pack**

30 and 60 enteric coated (resistant to stomach juices) soft capsules, oval, yellow, in folded carton

### **Marketing Authorisation Holder and Manufacturer**

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If you require further information about this medicine, please contact your local representative of the manufacturer)

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