

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### ANZIBEL PASTILLES – MENTHOL FLAVORED

5 mg + 4 mg + 3 mg, pastilles

CHLORHEXIDINE DIHYDROCHLORIDE, BENZOCAINE, ENOXOLONE

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*• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.*

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*• 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 only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

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#### What is in this leaflet?

1. What ANZIBEL is and what it is used for
2. Before you take ANZIBEL
3. How to take ANZIBEL
4. Possible side effects
5. How to store ANZIBEL
6. Further information

#### 1. WHAT ANZIBEL IS AND WHAT IS IT USED FOR

One pastille contains Chlorhexidine hydrochloride (chlorhexidine hydrochloride) 5mg, benzocaine (benzocaine) 4mg, enoxolone (enoxolone) 3mg as the active substances.

Effects of active substances in ANZIBEL pastilles complement each other, eliminating the discomfort caused by local irritation of the throat. Chlorhexidine has an antiseptic effect on the mucous membranes of the mouth and throat, enoxolone has antiinflammatory and benzocaine has anesthetic effect.

ANZIBEL pastilles are intended for local and temporary symptomatic relief of moderate infectious and inflammatory conditions of the mouth and throat, and sore throat without fever, caused by external factors such as smog, sudden changes in temperature and dust.

#### 2. BEFORE YOU TAKE ANZIBEL

##### **Do not use ANZIBEL**

- If you are allergic (hypersensitive) to the active substances or any other ingredients of ANZIBEL pastilles or any ester derivative with the anesthetic effect;
- If you have phenylketonuria (PKU).

**Take special care with ANZIBEL**

- Do not take doses higher than those specified in section 3;
- If you notice worsening of symptoms or if they last longer than 2 days, or if you have a fever, headache, nausea or vomiting, consult your doctor as soon as possible.

**Use in elderly**

- Note that the use of high doses, as well as long-term use can lead to increased blood pressure. Elderly may be more sensitive to benzocaine, as well as children, or weakened patients.

**Use in children**

- Do not give ANZIBEL pastilles menthol flavored to children under 6 years of age without consulting a doctor. Children may be more sensitive to benzocaine, as well as elderly or weakened patients.

**Use in athletes**

- If you play sport, keep in mind that this medicine contains benzocaine, which causes positive findings of doping control.

**Taking other medicines**

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

This medicine should not be taken with other medicines that are used in the mouth without consulting a doctor or pharmacist, even though it is not described in the recommended method of administration.

Interaction between benzocaine and cholinesterase inhibitors, ie sulfonamides is possible.

Anionic compounds and suspensions that are typically contained in toothpaste reduce the effectiveness of chlorhexidine, and so you should rinse the mouth after using toothpaste.

Interactions with diagnostic tests: ANZIBEL pastilles can have an impact on bentiromid test to determine the function of the pancreas. Do not take the medicine for at least 3 days prior to doing the test, and tell your doctor.

**Pregnancy and breastfeeding**

Contact your doctor or pharmacist before using the medicine.

- ANZIBEL pastilles should not be used by pregnant women, except with the permission of a doctor.

If pregnancy occurs during treatment, immediately contact a doctor.

**Breastfeeding**

Contact your doctor or pharmacist before using the medicine.

Active substances from ANZIBEL pastilles can pass into breast milk. If you use ANZIBEL pastilles, you should not breastfeed.

**Important information about some ingredients of ANZIBEL pastilles**

Each ANZIBEL pastille contains sorbitol as a sweetener. In case of intolerance to some sugars, contact your doctor before using this medicine. It may have a mild laxative effect. The caloric value is 2.6 kcal / g of sorbitol.

This medicine contains 0.5 mg of potassium acesulfame per pastille. This should be taken into account in patients with reduced renal function or in patients with controlled potassium diet.

**3. HOW TO TAKE ANZIBEL**

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.

**Adults and children over 12 years:**

1 pastille every 2 to 3 hours. The maximum dose is 8 pastilles daily.

**Children 6-12 years of age:**

1 pastille every 4 to 5 hours. The maximum dose is 6 pastilles daily.

If after 2 days you do not feel better or your condition gets worse, you should seek medical attention.

Unless your doctor tells you otherwise, carefully follow these instructions.

Your doctor will tell you how long you should use ANZIBEL pastilles.

If you think that the effect of ANZIBEL pastilles is too strong or too weak, talk to your doctor or pharmacist.

**If you take more ANZIBEL than you should**

If you take more medicine than you should, contact your doctor or pharmacist.

**If you forget to take ANZIBEL**

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

If you miss a dose, take the next dose at the usual time and continue to use the medicine as instructed by a doctor.

Talk to your doctor or pharmacist if you have any additional questions.

#### *4. POSSIBLE SIDE EFFECTS*

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

Side effects are listed according to the following categories of frequency:

**Very common:** more than 1 treated person of 10

**Common:** 1 to 10 treated persons of 100

**Uncommon:** 1 to 10 treated persons of 1000

**Rare:** 1 to 10 treated persons of 10000

**Very rare:** less than 1 treated person of 10000

**Not known:** frequency cannot be estimated from the available data

**Rare:**

- Generalized allergic reactions (sometimes with symptoms of runny nose, itching and skin rash);
- Irritation of the mouth, irritation of tip of the tongue;
- Pain, itching, swelling or redness in the mouth and around them;
- Disorders of the digestive system;
- Dysgeusia (taste disturbance);
- Edema (swelling due to fluid retention);
- High blood pressure (hypertension);
- Pigmentation of teeth.

Not all the side effects are mentioned here. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### *5. HOW TO STORE ANZIBEL*

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use ANZIBEL after the expiry date which is stated on the label.

Store in the original package.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### **What ANZIBEL contains**

The active substances are chlorhexidine dihydrochloride, benzocaine and enoxolone.  
Excipients: sorbitol (E420), acesulfame potassium (E950), magnesium stearate, menthol flavor.

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

White, round, biconvex pastilles. One side is smooth; the other has NOBEL logo engraved on it.

Contents: White opaque PVC-PE-PVDC / Al blister.

(20 pastilles / 2 blisters / 1 box) (10 pastilles / blister)

(30 pastilles / 3 blisters / 1 box) (10 pastilles / blister).

### **Regime of dispensing**

The medicine is issued without doctor's prescription.

### **Manufacturer**

NOBEL İLAÇ SANAYİİ VE TİCARET A. Ş., Ümraniye 34768 İstanbul Türkiye

### **Manufacturer of the medicinal product**

NOBEL İLAÇ SANAYİİ VE TİCARET A. Ş., Sancaklar 81100 Düzce Türkiye