

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

OtoAkut 50 mg/g + 10 mg/g ear drops, solution

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

1 g of solution contains 50 mg phenazone and 10 mg procaine hydrochloride.

1 drop of solution contains 2 mg phenazone and 0.4 mg procaine hydrochloride.

Excipient with known effect:

Contains 0.1 mg/g Butylated hydroxyanisole (E 320).

For the full list of excipients, see section 6.1.

### **3 PHARMACEUTICAL FORM**

Ear drops, solution

Clear, viscous, colourless to brownish solution

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

OtoAkut is indicated for the local symptomatic treatment of pain in the external auditory canal, namely for external ear infections and acute otitis media. It should only be used if the tympanic membran (eardrum) is intact.

#### **4.2 Posology and method of administration**

Posology

The single dose for adults and adolescents aged 15 years and older is 5 drops.

The single dose can be administered 3 to 4 times a day every 6 to 8 hours.

The use of OtoAkut is only intended for short-term symptomatic pain relief. If the pain does not subside within 2 days, the treatment should be reconsidered. The same applies to an intensification of the symptoms during treatment.

The usual duration of treatment is 5 days. The duration of treatment is unlimited under medical supervision.

#### *Paediatric population*

For toddlers and children up to 14 years of age, the single dose is 2 to 3 drops.

The single dose can be administered 3 to 4 times a day every 6 to 8 hours.

#### Method of administration

For auricular use only.

OtoAkut should be used at body temperature (content briefly warmed up by holding the bottle in the hand. Do not heat!). OtoAkut is administered into the auditory canal of the affected ear when the patient is lying on the side with the affected ear upwards. One drop at a time is released by briefly and lightly squeezing the bottle.

The lateral position is then maintained for about 15 minutes so that the ear drops can act on the eardrum.

The ear is loosely closed by packing it with cotton wool, which should be removed at the end of treatment.

### **4.3 Contraindications**

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1
- Hypersensitivity to pyrazolone (e.g. medicinal products containing metamizole, isopropylaminophenazone, propylphenazone or phenazone) or to medicinal products containing phenylbutazone
- Perforation of the tympanic membrane (eardrum) or inflammation of the ear canal with injured skin.
- Certain metabolic diseases (hepatic porphyria, congenital glucose-6-phosphate dehydrogenase deficiency)

### **4.4 Special warnings and precautions for use**

Before the beginning of treatment with the medicinal product, it is recommended to check if there is perforation of the tympanic membrane. If the tympanic membrane is perforated, intra-auricular administration may lead to contact of the product with middle ear structures and cause undesirable effects in these tissues.

The product should not be used in the presence of a perforated tympanic membrane, which would include the presence of a myringotomy, in case of penetration of the active substances into the middle ear, risking ototoxicity. The patient should be advised that treatment should be stopped, and medical advice sought, if ear discharge develops during the course of treatment, which may indicate perforation.

If symptoms do not improve within 2 days or worsen rapidly or significantly at any time, the therapy should be re-evaluated.

Methemoglobinemia has been reported following the topical use of local anaesthetics. Caution should be exercised in patients who are susceptible to methemoglobinemia, including infants under 3 months of age and patients with haemoglobinopathies or Glucose-6-phosphate dehydrogenase (G6PD) deficiency.

Patients should be advised to avoid letting OtoAkut come into contact with eyes or nose. If contact occurs, the eyes or nose should be rinsed out immediately with plenty of water.

If orally ingested by mistake, local numbness of the tongue and oral cavity may occur. This may lead to difficulty in swallowing. In this case the oral cavity should be rinsed out immediately with plenty of water and medical advice should be searched.

#### Paediatric population

A medical examination is required before using this medicinal product in children under the age of 3 years.

Butylated hydroxyanisole (E 320) may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

### **4.5 Interaction with other medicinal products and other forms of interaction**

No interaction studies have been performed.

Simultaneous treatment with sulfonamides and benzylpenicillin should be avoided because of the risk of incompatibility.

### **4.6 Fertility, pregnancy and lactation**

#### Pregnancy

There are no or limited amount of data from the use of phenazone/procaine hydrochloride in pregnant women and there are no studies on the reproductive toxicity of this combination of active substances (see section 5.3). Therefore, OtoAkut should not be used during pregnancy unless the clinical condition of the woman requires treatment with phenazone/procaine hydrochloride. In this case, it should only be used for a short time and at the lowest effective dose.

#### Breastfeeding

It is unknown whether phenazone/metabolites or procaine /metabolites are excreted in human milk.

A risk to the newborns/infants cannot be excluded.

OtoAkut should not be used during breast-feeding.

#### **4.7 Effects on ability to drive and use machines**

OtoAkut has no or negligible influence on the ability to drive and use machines.

If used as intended, the ear canal is closed with cotton wool after the application of this medicinal product. The cotton wool can affect hearing and thus the ability to react in traffic, operate machines or work without a secure hold. In these cases, the ability to drive and use machines may be impaired.

#### **4.8 Undesirable effects**

Adverse reactions are listed below by system organ class and frequency.

*Very rare (<1/10,000):*

Immune system disorders: Hypersensitivity reactions such as skin reactions or nettle rash

##### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

#### **4.9 Overdose**

When used locally in the ear, overdoses or intoxications are unlikely.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Otologicals; analgesics and anaesthetics; combinations, ATC code: S02DA30

OtoAkut is a combined medicinal product that contains phenazone and procaine hydrochloride.

Phenazone is a pyrazolone derivative with analgesic, antipyretic and minor anti-inflammatory properties. Procaine hydrochloride has a local anaesthetic effect.

## **5.2 Pharmacokinetic properties**

There are no data from pharmacokinetic studies in humans.

## **5.3 Preclinical safety data**

No animal experiments on the teratogenic and embryotoxic potential have been carried out for phenazone and procaine.

Phenazone showed no mutagenic effects in several in vivo and in vitro tests. In vitro genotoxicity studies with procaine were negative. A long-term carcinogenicity study with phenazone in rats showed weakly positive effects in the kidney area. Thus, a tumorigenic effect cannot be excluded with certainty.

Procaine showed no signs for increased tumor incidences in a 3-year study in rats. Further long-term studies to assess the carcinogenic potential of procaine are not available.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Glycerol (E 422)

Butylated hydroxyanisole (E 320)

## **6.2 Incompatibilities**

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

## **6.3 Shelf life**

2 years

3 months after first opening of the dropper container.

## **6.4 Special precautions for storage**

Do not store above 25 °C.

Store in the original package, in order to protect from light.

#### **6.5 Nature and contents of container**

Dropper container made of LDPE, with a screw-cap made of HDPE. Each bottle contains 10 g of solution.

#### **6.6 Special precautions for disposal**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

### **7 MARKETING AUTHORISATION HOLDER**

INFECTOPHARM Arzneimittel und Consilium GmbH  
Von-Humboldt-Straße 1  
64646 Heppenheim  
Germany

### **8 MARKETING AUTHORISATION NUMBER(S)**

PL 15011/0040

### **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

17/09/2024

### **10 DATE OF REVISION OF THE TEXT**

17/09/2024