## RELY ON TRISPORIN® FOR THE TREATMENT OF BACTERIAL INFECTIONS SUCH AS:

- Chronic bronchitis
- Maxillary sinusitis
- Pharyngitis/tonsillitis
  - Pneumonia
- Uncomplicated skin infections
  - Acute bacterial otitis media

TABLETS - ADULTS AND ADOLESCENTS (>13 years old)		
Infections of skin and skin structures Pneumonia	300 mg (1 tablet) every 12 hours for 10 days	
Other infections	300 mg every 12 hours or 600 mg every 24 hours	

SUSPENSION - CHILDREN AGED 6 MONTHS TO 12 YEARS		
9 kg	2.5 ml every 12 hours or 5 ml every 24 hours for 5 to 10 days	
18 kg	5 ml every 12 hours or 10 ml every 24 hours for 5 to 10 days	
27 kg	7,5 ml every 12 hours or 15 ml every 24 hours for 5 to 10 days	
36 kg	10 ml every 12 hours or 20 ml every 24 hours for 5 to 10 days	
≥ 43 kg	12 ml every 12 hours or 24 ml every 24 hours for 5 to 10 days	
The total daily dose is 14 mg / kg without exceeding the maximum dose of 600 mg / day		

#### DAFRA PHARMA INTERNATIONAL

#### Headquarters

Slachthuisstraat 30/7 2300 Turnhout – Belgium



Setting the standard

# **Trisporin®**

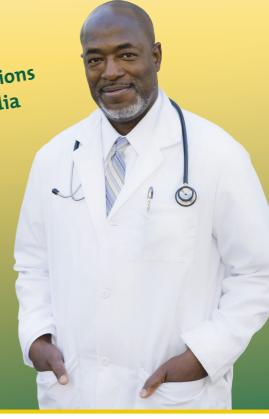
EUROPEAN

**Cefdinir** 

# RELY ON TRISPORIN® FOR THE TREATMENT OF BACTERIAL INFECTIONS SUCH AS:

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  - Acute bacterial otitis media







Setting the standard

# Trisporin<sup>®</sup>

## WHAT IS TRISPORIN® AND WHAT IT IS USED FOR?

TRISPORIN® contains cefdinir, which is a cephalosporin antibiotic. It works by killing sensitive bacteria. It is used in the treatment of bacterial infections such as middle ear infections, acute bacterial otitis media, acute maxillary sinusitis, acute bacterial rhinosinusitis, pharyngitis/tonsillitis,uncomplicated skin infections (ATC code: Jo1DD15).

## WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRISPORIN®:

Do not take it if you are allergic to any ingredient in it or to any other cephalosporin antibiotic.

**Surgical procedure or medical test:** Inform your doctor and surgeon in case you are taking this medication.

**Taking with other medicines:** Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription, they may interfere with the actions of TRISPORIN®.

- TRISPORIN® should be taken at least 2 hours before or after intake of an anti acid medicine.
- As with other drugs, probenecid inhib its the renal excretion of cefdinir.
- If you combine TRISPORIN® with iron containing drugs, it should be taken at least 2 hours before or after this drug.

• Taking with alcohol: alcohol may interfere with the actions of the medicine.

**Pregnancy and breastfeeding:** If you are pregnant, thinking of becoming pregnant or breastfeeding, TRISPORIN® should not be taken unless told to do so by your doctor

**Driving or using machinery:** Adverse effects on the ability to drive or operate machinery have not been observed.

#### **HOW TO TAKE TRISPORIN®?**

TRISPORIN® Tablets: Adults and children aged more than 13 years: total daily dose is 300 to 600 mg per day (1 to 2 tablets per day).

TRISPORIN® suspension: Children aged 6 months to 12 years: total daily dose is 14 mg/kg up to a maximum dose of 600 mg per day. TRISPORIN® Suspension may be administrated with or without food.

Weight	Quantity of suspension (125 mg/5 ml) to be administered
9 kg	2.5 ml every 12 hours or 5 ml every 24 hours for 5 to 10 days
18 kg	5 ml every 12 hours or 10 ml every 24 hours for 5 to 10 days
27 kg	7,5 ml every 12 hours or 15 ml every 24 hours for 5 to 10 days
36 kg	10 ml every 12 hours or 20 ml every 24 hours for 5 to 10 days
≥ 43 kg	12 ml every 12 hours or 24 ml every 24 hours for 5 to 10 days

Directions for mixing and use of the oral suspension: Put clean and fresh water up to the half level of the sign on the bottle, than shake well, wait for 5 minutes to get a homogeneous dispersal. Add water up to the sign level and then shake again. CLOSE THE BOTTLE TIGHTLY AFTER EACH USE. After mixing, the suspension is stored at controlled room temperature; it may be used for 10 days after which any unused portion should be discarded.

If you forgot to take TRISPORIN®, take it as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take 2 doses at once.

#### **POSSIBLE SIDE EFFECTS:**

They are mild and self-limiting. Most common reported side effects are: diarrhea, vaginal moniliasis, nausea, headache, abdominal pain, vaginitis. If you get any side effects, talk to your doctor or pharmacist. This includes any

possible side effect not listed in this leaf-

let.

#### **HOW TO STORE TRISPORIN®?**

Store below 30°C in in its original package. Keep out of reach and sight of children. Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.

#### WHAT TRISPORIN® CONTAINS:

#### TRISPORIN® Tablets:

Cefdinir, Calcium Carmellose,

Microcrystalline Cellulose, Macrogol Stearate, Magnesium Stearate, Colloidal Anhydrous Silica. The filmcoating contains: Hypromellose, Titanium Dioxide, Macrogol 400.

#### TRISPORIN® suspension:

Cefdinir, Citric Acid, Sodium Citrate, Sodium Benzoate, Xanthan Gum, Guar Gallactomannan, colloidal silica, Magnesium Stearate, Strawberry Flavour, Cream Flavour, Sucrose.

#### **HOW IS TRISPORIN® PACKAGED?**

#### TRISPORIN® Tablets:

10 tablets in a blister.

#### TRISPORIN® suspension:

Cream-yellow powder in a 100 ml scaled glass bottle with plastic screw-cap and a measuring spoon.

TRISPORIN® is a prescription only medicine. DO NOT USE WITHOUT CONSULTING YOUR PHYSICIAN.

