**Patient Information Leaflet**

**TRISPORIN® Suspension**

**Cefdinir 125 mg/5 ml Powder For Oral Suspension**

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

**for you.** Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or pharmacist. If you get any side effects, talk to 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.

***Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.***

1. **What TRISPORIN® Suspensionis and what it is used for:**

TRISPORIN® Suspensioncontains 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: J01DD15).

1. **What you need to know before you take TRISPORIN® Suspension:**

* **Do not take it** if you are allergic to any ingredient in it (see section 6) 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® Suspension.
  + TRISPORIN® Suspensionshould be taken at least 2 hours before or after intake of an **antiacid** medicine.
  + As with other drugs, **probenecid** inhibits the renal excretion of cefdinir.
  + If you combine TRISPORIN® Suspensionwith **iron** containing drugs, it should be taken at least 2 hours before or after this drug.
  + **Taking with alcohol: a**lcohol may interfere with the actions of the medicine.
* **Pregnancy and breast−feeding:** If you are pregnant, thinking of becoming pregnant or breast−feeding, TRISPORIN® Suspension 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.

1. **How to take TRISPORIN® Suspension:**

* **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.
* Children aged 6 months to 12 years: total daily dose is 14 mg/kg up to a maximum dose of 600 mg per day:

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| *Weight* | *Quantity of suspension (125 mg/5 ml) to be administered* |
| 9 kg | 2.5 ml per 12 hours or 5 ml single daily dose for 5 to 10 days |
| 18 kg | 5 ml per 12 hours or 10 ml single daily dose for 5 to 10 days |
| 27 kg | 7.5 ml per 12 hours or 15 ml single daily dose for 5 to 10 days |
| 36 kg | 10 ml per 12 hours or 20 ml single daily dose for 5 to 10 days |
| >43 kg | 12 ml per 12 hours or 24 ml single daily dose for 5 to 10 days |

* Trisporin**®** Suspension may be administrated with or without food.
* **If you forgot to take TRISPORIN® Suspension,** 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**.**

1. **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 leaflet.**

1. **How to store TRISPORIN® Suspension**: Store below 30oC 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.
2. **Other information**

**What TRISPORIN® Suspension contains**: Cefdinir, Citric Acid, Sodium Citrate, Sodium Benzoate, Xanthan Gum, Guar Gallactomannan, Silicon Dioxide, Magnesium Stearate, Strawberry Flavour, Cream Flavour, Sucrose.

**How is Trisporin**® **Suspension packaged:** cream-yellow powder in a 100 ml scaled glass bottle with plastic screw-cap and a measuring spoon.

**Trisporin**® **Suspension** is a prescription only medicine.

**Manufacturer:** PharmaVision Sanayi ve Ticaret A. Ş., Davutpaşa Cad. No: 145? 34010 Topkapı / Istanbul, Turkey.

**Marketing Authorisation Holder:** Dafra Pharma GmbH, Mühlenberg 7, 4052 Basel, Switzerland.

**Date of Revision of This Text:** March 2016.