



## Cinnarizine + dimenhydrinate, 20 mg + 40 mg, tablets

### Key facts about active substances:

- **Dimenhydrinate** acts as antihistamine with anticholinergic properties, exerting parasympatholytic and centrally-depressant effects. The substance exhibits antiemetic and antivertiginous effects through influencing the chemoreceptor trigger zone in the region of the 4th ventricle. Dimenhydrinate thus acts predominantly on the central vestibular system.
- Due to its calcium antagonistic properties, **cinnarizine** acts mainly as a vestibular sedative through inhibition of the calcium influx into the vestibular sensory cells. Cinnarizine thus acts predominantly on the peripheral vestibular system.
- Both cinnarizine and dimenhydrinate are known to be effective in the treatment of vertigo. The combination product is more effective than the individual compounds in the population studied.
- Reference product Arlevert (HENNIG ARZNEIMITTEL GmbH & Co. KG) has been registered in UE market in 2005.
- Vertigo is one of the most common reasons that people go to a physician. Overall, vertigo and balance disorders affects as much as 20-30% of adult population and 8-18% of children. . However, this condition becomes more common as a person ages and as much as 40% of the 40-and-over population will experience vertigo at some point.

**Therapeutic classification:** antivertigo preparations, ATC code: N07CA52.

### Therapeutic indications:

Treatment of vertigo symptoms of various origins.

### **Project status:**

Completed stages (IP rights and know-how for the documentation):

- Pharmacokinetic study to investigate the pharmacokinetic profile and intra-subject variability of active substances has been conducted with the reference product.
- Analytical methods for characterization of API and drug product have been validated.
- The drug product formulation has been preliminary developed.