Only for the use of Medical Professionals

Armoda®

Armodafinil

Description

Armoda® is a preparation of Armodafinil which is an indirect dopamine receptor agonist. Armodafinil is the R-enantiomer of Modafinil which is a 1:1 mixture of the R- and S-enantiomers. **Armoda**® binds to the dopamine transporter and inhibits dopamine reuptake. As a result, **Armoda**® increases neuronal activity in the hypothalamus, enhances activity in hypothalamic wakefulness center (TMN, tuberomammillary nucleus) within the hypothalamic sleep wake switch.

Indications

Armoda® is indicated to improve wakefulness in adult patients with-

- Obstructive sleep apnea (OSA)
- Narcolepsy
- Shift work disorder (SWD)

Dosage and administration

Adults

Obstructive Sleep Apnea (OSA) & Narcolepsy

150 mg to 250 mg as a single dose in the morning.

Shift Work Disorder (SWD)

150 mg as a single dose approximately 1 hour prior to the start of work shift.

Children

Safety and effectiveness in pediatric patients less than 17 years of age have not been established.

Elderly

In elderly patients, elimination of Armodafinil and its metabolites may be reduced as a consequence of aging. Therefore, consideration should be given to the use of lower doses and close monitoring in this population.

Patients with hepatic impairment

In patients with severe hepatic impairment, Armodafinil should be administered at a reduced dose.

Patients with renal impairment

There is inadequate information to determine safety and efficacy of dosing in patients with severe renal impairment.

Use in pregnancy and lactation

Pregnancy

There are no adequate and well controlled studies of Armodafinil in pregnant women. Armodafinil should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation

It is not known whether Armodafinil or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Armodafinil is administered to a nursing woman.

Side effects
The most common side effects of Armodafinil are serious rash, including Stevens-Johnson syndrome, angioedema and anaphylaxis reactions, multi-organ hypersensitivity reactions, persistent sleepiness, psychiatric symptoms and some cardiovascular events.

Contraindications
Armoda® is contraindicated in patients with known hypersensitivity to Armodafinil or any of the excipients of this product.

Precautions
Patients should be cautioned about operating an automobile or other hazardous machinery until it is reasonably certain that Armodafinil therapy will not adversely affect their ability to engage in such activities. Caution should be taken in treating patients with a history of psychosis, depression or mania. Discontinuation of treatment should be considered if psychiatric symptoms develop. Increased monitoring of heart rate and blood pressure should be exercised. Caution should be exercised when prescribing Armodafinil to patients with known cardiovascular disease.

Drug interactions
The clearance of drugs that are substrates for CYP3A4 or CYP3A5 (e.g., steroidal contraceptives, Cyclosporine, Midazolam and Triazolam) may be increased by Armodafinil which results in lower systemic exposure. Dosage adjustment of these drugs should be considered when used concomitantly with Armodafinil.

Elimination of drugs that are substrates for CYP2C19 (e.g., Phenytoin, Diazepam, Propranolol, Omeprazole and Clomipramine) may be prolonged by Armodafinil which results in higher systemic exposure. Dosage adjustment of these drugs should be considered when used concomitantly with Armodafinil.

More frequent monitoring of prothrombin times/ International normalized ratio (INR) should be considered whenever Armodafinil is co-administered with Warfarin.

Caution should be used when concomitantly administering MAO inhibitors and Armodafinil.

Overdose
There were no overdoses reported in the Armodafinil clinical studies. Symptoms of Armodafinil overdose are likely to be similar to those of Modafinil which included excitation or agitation, insomnia and slight or moderate elevations in hemodynamic parameters. There is no specific antidote for Armodafinil overdose. However, if overdose occurs, it should be managed with primary supportive care.

Pharmaceutical precautions
Store in a cool (below 25°C) and dry place protected from light.

Presentation
Armoda® 150 tablet: Each tablet contains Armodafinil INN 150 mg.
Armoda® 250 tablet: Each tablet contains Armodafinil INN 250 mg.

Package quantities
Armoda® 150 tablet: Carton of 30 tablets in blister pack.
Armoda® 250 tablet: Carton of 30 tablets in blister pack.

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