

HERPEX 800 DT

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Abbreviated Prescribing information for HERPEX 800 DT (Aciclovir 800mg Dispersible Tablet I.P.)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Aciclovir is an antiviral agent which is highly active in vitro against herpes simplex virus (HSV) types I and II and varicella zoster virus. Aciclovir is phosphorylated after entry into herpes infected cells to the active compound aciclovir triphosphate which acts as an inhibitor of, and substrate for, the herpes-specified DNA polymerase, preventing further viral DNA synthesis without affecting the normal cellular processes.

INDICATION: For the treatment of varicella (chickenpox) and herpes zoster (shingles) infections.

DOSAGE AND ADMINISTRATION: Herpes zoster infections in adults: 800mg aciclovir five times daily at approximately four-hourly intervals (omitting the night time dose) for 7 days. Varicella infection in children: Children aged 6 years and over be given 800mg four times daily for 5 days. Dosing may be more accurately calculated as 20mg/kg bodyweight (not to exceed 800mg four times daily). Special attention should be given to dosage reduction in elderly patients and with impaired renal function. Administration: Patients who experience difficulty in swallowing the tablets may disperse them in a minimum of 50ml water which should be stirred before drinking.

CONTRAINDICATION: Contraindicated for patients who develop hypersensitivity to acyclovir or valacyclovir.

WARNINGS & PRECAUTIONS: Renal failure, in some cases resulting in death. Thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), which has resulted in death. Caution should also be exercised when administering Aciclovir to patients receiving potentially nephrotoxic agents since this may increase the risk of renal dysfunction and/or the risk of reversible central nervous system symptoms such as those that have been reported in patients treated with intravenous acyclovir. Adequate hydration should be maintained. Thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (TTP/HUS), which has resulted in death, has occurred in immunocompromised patients receiving acyclovir therapy.

DRUG INTERACTIONS: Interact with ciclosporin, cimetidine, probenecid, mycophenolate mofetil, theophylline and zidovudine when administered concomitantly.

ADVERSE REACTIONS: Common: headache, dizziness, nausea, vomiting, diarrhoea, abdominal pains, pruritus, rashes (including photosensitivity), fatigue and fever. Uncommon: urticaria and accelerated diffuse hair loss. Rare: anaphylaxis, dyspnoea, reversible rises in bilirubin and liver related enzymes, angioedema and increases in blood urea and creatinine. Very rare: anaemia, leukopenia, thrombocytopenia, agitation, confusion, tremor, ataxia, dysarthria, hallucinations, psychotic symptoms, convulsions, somnolence, encephalopathy, coma, hepatitis, jaundice, acute renal failure and renal pain.

MARKETED BY:



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IN/ HERPEX 800 DT/FEB 2015/01/AbPI
(Additional information is available on request)