

BASIC SUCCINCT STATEMENT: VOLTAFLAM® TH / VOVERAN® TH

Presentation: Each hard gelatin capsule contains Diclofenac Sodium IP 50 mg (as gastro-resistant tablets) and Thiocolchicoside IP 4 mg (as uncoated tablet). **Indications:** For treatment of acute inflammatory conditions associated with spasm in adults only. **Dosage:** The recommended daily dosage is one capsule twice a day. The maximum recommended dose of Thiocolchicoside is 16 mg daily in divided dose and for Diclofenac Sodium IP is 150 mg daily. The dose should not exceed maximum daily recommended dose. The treatment duration is limited to 7 consecutive days. The dose should be adjusted individually as a general recommendation. Adverse effects may be minimized by using the lowest effective dose for shortest duration necessary to control symptoms. **Contraindications:** Hypersensitivity to the active substances or any of the excipients • Active, gastric or intestinal ulcer, bleeding or perforation. • History of gastrointestinal bleeding or perforation, relating to previous NSAID therapy • Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding) • Last trimester of pregnancy • Hepatic failure • Renal failure • Established congestive heart failure (NYHA11-1V), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease. • Like other non-steroidal anti-inflammatory drugs (NSAIDs), diclofenac is also contraindicated in patients in whom attacks of asthma, angioedema, urticaria or acute rhinitis are precipitated by ibuprofen, acetylsalicylic acid or other nonsteroidal anti-inflammatory drugs. **Warnings/Precautions:** The concomitant use of Diclofenac with systemic NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided due to the absence of any evidence demonstrating synergistic benefits and the potential for additive undesirable effects. • Caution is indicated in the elderly on basic medical grounds. In particular, it is recommended that the lowest effective dose be used in frail elderly patients or those with a low body weight. The elderly have increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal. To reduce the risk of GI toxicity in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation, and in the elderly, the treatment should be initiated and maintained at the lowest effective dose. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant use of medicinal products containing low dose acetylsalicylic acid (ASA/aspirin or medicinal products likely to increase gastrointestinal risk. • Caution is recommended in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as systemic corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors (SSR1s) or anti-platelet agents such as acetylsalicylic acid. • Close medical surveillance and caution should be exercised in patients with ulcerative colitis, or with Crohn's disease as these conditions may be exacerbated. • Close medical surveillance is required when prescribing diclofenac to patients with impairment of hepatic function as their condition may be exacerbated. • **Renal effects:** As fluid retention and oedema have been reported in association with NSAIDs therapy, including diclofenac, particular caution is called for in patients with impaired cardiac or renal function. • **Cardiovascular and cerebrovascular affects:** Patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidemia, diabetes mellitus, and smoking) should only be treated with diclofenac after careful consideration. • **Haematological effects:** Use of diclofenac is recommended only for short-term treatment. Diclofenac may reversibly inhibit platelet aggregation. Patients with defects of haemostasis, bleeding diathesis or haematological abnormalities should be carefully

monitored. • **Female fertility:** The use of diclofenac may impair female fertility and is not recommended in women attempting to conceive. In women who may have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of Diclofenac should be considered. **Drug Interactions:** • Caution with concomitant use of diuretics and antihypertensives (e.g. beta blockers, ACE inhibitors), methotrexate, other NSAIDs and corticosteroids, SSRIs. • Monitoring recommended for patients receiving anticoagulants, anti-platelets agents as well as blood glucose level if used concomitantly with antidiabetics. • Monitoring of serum lithium or digoxin levels recommended if used concomitantly. • Dose of diclofenac to be reduced in patients receiving ciclosporin. • Interactions with concomitant use of quinolone antibacterials, CYP2C9 inhibitors (e.g. sulfapyrazone, voriconazole). • Monitoring of phenytoin plasma concentrations is recommended if used concomitantly. • **Salicylamide:** Salicylamide prolongs the elimination half-life of paracetamol and increases the accumulation of hepatotoxic metabolites. • **Chlorzoxazone:** Co-administration of paracetamol and chlorzoxazone enhances the hepatotoxicity of both substances. • **Zidovudine:** Concomitant use of zidovudine and paracetamol increases the tendency to neuropenia. **Fertility, pregnancy and lactation:** • **Pregnancy:** Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/ foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and or cardiac malformation after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1% up to approximately 1.5%. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has shown to result in increased pre and post-implantation loss and embryo-foetal lethality. Voltaflam TH 4 is contraindicated in pregnancy and in women of child bearing potential who are not using effective contraceptive. • **Lactation:** Like other NSAIDs, Diclofenac passes into breast milk in small amounts and Thiocolchicoside is contraindicated in breast-feeding. Hence, Voltaflam TH4 should not be administered in lactating mothers. • **Fertility:** Voltaflam TH 4 may impair female fertility and is not recommended in women attempting to conceive. **Effects on ability to drive and use machines:** Patients who experience visual disturbances, dizziness, vertigo, somnolence, central nervous system disturbances, drowsiness or fatigue while taking NSAIDs should refrain from driving or operating machinery. **Warning:** Not for veterinary use. **Packs:** Pack of 10X10 hard gelatin capsules. India BSS dated 28 Aug 20 based on the Pack insert dated 13th Aug 2019.

Marketed by: (Under agreement with Novartis India Limited) Dr. Reddy's Laboratories Ltd., Global Distribution Centre, Survey No. 41, Bachupally (V), Bachupally (M), Medchal - Malkajgiri (Dist.), Hyderabad – 500090, Telangana, India.

For the use of a registered medical practitioner or a hospital or a laboratory only.

India BSS dtd 20 Mar 2018 based on international BSS dtd 5 Feb 2018 effective from 10 Sep 18.

Please note the link to the HCP Privacy Notice - <https://www.novartis.in/general-privacy-notice-business-partners>.