TAJ DRUG WORLD

FETRASIL
(Sibutramine Hydrochloride Monohydrate)

Fetrasil

(sibutramine hydrochloride monohydrate)

Each Fetrasil Tablets contains 5 mg, 10 mg, and 15 mg of sibutramine hydrochloride monohydrate. It also contains as inactive ingredients: lactose monohydrate, NF; microcrystalline cellulose, NF; colloidal silicon dioxide, NF; and magnesium stearate, NF in a hard-gelatin Tablets [which contains titanium dioxide, USP; gelatin; FD&C Blue No. 2 (5- and 10-mg Tabletss only)

weight lossFetrasil is indicated for the management of obesity, including weight loss and maintenance of weight loss, and should be used in conjunction with a reduced calorie diet. Fetrasil is recommended for obese patients with an initial body mass index = 30 kg/m2, or = 27 kg/m2 in the presence of other risk factors (e.g., diabetes, dyslipidemia, controlled hypertension).

DOSAGE AND ADMINISTRATION

The recommended starting dose of Fetrasil is 10 mg administered once daily with or without food. If there is inadequate weight loss, the dose may be titrated after four weeks to a total of 15 mg once daily. The 5 mg dose should be reserved for patients who do not tolerate the 10 mg dose. Blood pressure and heart rate changes should be taken into account when making decisions regarding dose titration (see WARNINGS and PRECAUTIONS).

Doses above 15 mg daily are not recommended. In most of the clinical trials, Fetrasil was given in the morning.

Storage

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F) [see USP controlled room temperature]. Protect Tabletss from heat and moisture. Dispense in a tight, light-resistant container as defined in USP.

WARNINGS

Blood Pressure and Pulse

Fetrasil SUBSTANTIALLY INCREASES BLOOD PRESSURE AND/OR PULSE RATE IN SOME PATIENTS. REGULAR MONITORING OF BLOOD PRESSURE AND PULSE RATE IS REQUIRED WHEN PRESCRIBING Fetrasil. In placebo-controlled obesity studies, sibutramine 5 to 20 mg once daily was associated with mean increases in systolic and diastolic blood pressure of approximately 1 to 3 mm Hg relative to placebo, and with mean increases in pulse rate relative to placebo of approximately 4 to 5 beats per minute. Larger increases were seen in some patients, particularly when therapy with sibutramine was initiated at the higher doses (see table below). In premarketing placebo-controlled obesity studies, 0.4% of patients treated with sibutramine were discontinued for hypertension (SBP = 160 mm Hg or DBP = 95 mm Hg),

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compared with 0.4% in the placebo group, and 0.4% of patients treated with sibutramine were discontinued for tachycardia (pulse rate = 100 bpm), compared with 0.1% in the placebo group. Blood pressure and pulse should be measured prior to starting therapy with Fetrasil and should be monitored at regular intervals thereafter. For patients who experience a sustained increase in blood pressure or pulse rate while receiving Fetrasil, either dose reduction or discontinuation should be considered. Fetrasil should be given with caution to those patients with a history of hypertension (see DOSAGE AND ADMINISTRATION), and should not be given to patients with uncontrolled or poorly controlled hypertension.

Fetrasil Tablets

PRECAUTIONS

Pulmonary Hypertension

Certain centrally-acting weight loss agents that cause release of serotonin from nerve terminals have been associated with pulmonary hypertension (PPH), a rare but lethal disease. In premarketing clinical studies, no cases of PPH have been reported with sibutramine Tabletss. Because of the low incidence of this disease in the underlying population, however, it is not known whether or not Fetrasil may cause this disease.

Seizures

During premarketing testing, seizures were reported in < 0.1% of sibutramine treated patients. Fetrasil should be used cautiously in patients with a history of seizures. It should be discontinued in any patient who develops seizures

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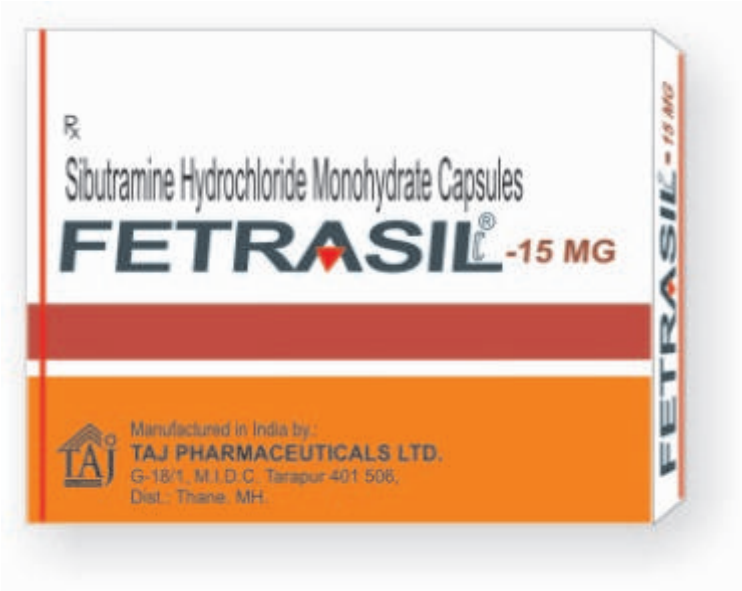
Bleeding

There have been reports of bleeding in patients taking sibutramine. While a causal relationship is unclear, caution is advised in patients predisposed to bleeding events and those taking concomitant medications known to affect hemostasis or platelet function.

Presentation

Fetrasil Tablets Blister of 10 Tablets



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