ZULTRACET

COMPOSITION:

Senna Leaf Extract (M.S).....50mg
Rhubarb Extract (M.S) 25mg
Peppermint Oil (B.P)..... 0.5mg
Fennel Oil (U.ZULTRA 50mg Tablets
Each tablet contains:
Tramadol HCl (B.P.) 50mg
Product conforms to the Manufacturer's Specifications.

DESCRIPTION:

The chemical name for Tramadol Hydrochloride is (±) cis-2-[(dimethylamino)methyl]1-(3-methoxyphenyl) cyclohexanol hydrochloride. The molecular weight of Tramadol Hydrochloride is 299.84. Tramadol Hydrochloride is a white, bitter, crystalline, and odorless powder.
The chemical name for Acetaminophen is N-acetyl-p-aminophenol. The molecular weight of Acetaminophen is 151.17. Acetaminophen is an analgesic and antipyretic agent which occurs as a white, odorless, crystalline powder, possessing a slightly bitter taste.

INDICATIONS:

Acute and Chronic Pain. Pain accompanied with diagnostic procedures, post surgical pains, labour pain, colic and trauma.

CONTRAINDICATIONS:

Acute intoxication with alcohol, hypnotics, analgesics or psychotropic drugs.
USE DURING PREGNANCY : In accordance with currently prevailing recommendations, medication with the preparation during pregnancy should only be resorted to after careful consideration of the risks. So far no reports are available on its use during lactation.

SIDE EFFECTS:

Sweating, dizziness, nausea, vomiting, dry mouth and fatigue may occur after Tramadol HCl (ZULTRA) & Tramadol HCl+ Acetaminophen (ZULTRACET) administration. It is also possible that the preparation may affect the cardiovascular system. Undesirable effects occur particularly when the patient is under physical strain. Respiratory depression has so far not been observed during treatment with Tramadol HCl (ZULTRA) & Tramadol HCl+ Acetaminophen (ZULTRACET) tablets. However, it cannot definitely be ruled out if the recommended dosage is considerably exceeded or on the concomitant administration of other centrally depressant drugs.

DRUG-DRUG INTERACTIONS:

On the concomitant administration of Tramadol HCl (ZULTRA) & Tramadol HCl+ Acetaminophen (ZULTRACET) with substances which also act on the central nervous system (e.g. Tranquillizers, Hypnotics) the sedative effects may be intensified. At the same time, however, combining Tramadol HCl (ZULTRA) & Tramadol HCl+ Acetaminophen (ZULTRACET) with a tranquillizer, for example, will probably have a favourable effect on pain sensation. Tramadol HCl (ZULTRA) & Tramadol HCl+ Acetaminophen (ZULTRACET) should not be used in patients receiving MAO (Mono Amine Oxidase) inhibitors.

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DOSAGE & ADMINISTRATION:

·The dosage should be adjusted to the intensity of the pain.
·Single dose for adults and adolescents over 14 years of age.
·1 - 2 tablets to be taken with a little liquid 3-4 times daily.
·In general the daily dose should not exceed 400 mg of Tramadol HCl.
·In impaired renal or hepatic function, it may be necessary to adjust the dose.

DURATION OF TREATMENT:

During long term treatment with Tramadol HCl (ZULTRA) & Tramadol HCl+ Acetaminophen (ZULTRACET) the possibility of dependance cannot be entirely excluded. Therefore, the physician is to decide on the duration of treatment and whether the preparation is to be withdrawn temporarily. Tramadol HCl (ZULTRA) & Tramadol HCl+ Acetaminophen (ZULTRACET) should not be used for longer than therapeutically necessary.

PRECAUTIONS:

Even when administered according to instructions the preparation may affect the reaction ability of the patient to such an extent that his capacity to drive or operate machines may be impaired. This applies particularly in conjunction with alcohol. The preparation should be used with care in patients with increased sensitivity to opioids.

STORAGE:

Protect from light, excessive heat & moisture.
Store in a cool & dry place below 30OC.
Keep out of reach of children.

PRESENTATION:

ZULTRA Tablets 50 mg are available in blister pack of 20's.
ZULTRA CET Tablets are available in blister pack of 20's.