MABRON (Tramadol hydrochloride)

Composition	2ml solution for injection contain 100mg of Tramadol Hydrochloride. This is equivalent to one ampoule **MABRON.** The chemical designation is (+)-trans-2-(dimethylaminomethyl)-1-(m-methoxyphenyl)-cyclohexanol-hydrochloride.
Indications	Moderate to intense pain, diagnosis measures and surgical pain.
ContraIndications	Acute intoxication with alcohol, hypnotics, analgesics or other CNS-acting drugs. Note: 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. The preparation should be used with care in patients with increased reactivity to opioids. Contraindicated in respiratory depression, in excessive bronchial secretion, in the presence of acute alcoholism, head injuries & in conditions in which intracranial pressure is raised. It should not be given during an attack of bronchial asthma or heart failure secondary to chronic lung disease. It should be given with caution or in reduced doses to patients with hypothyroidism, adrenocortical insufficiency, impaired kidney or liver function, prostatic hypertrophy or shock. It should be used with caution in patients with obstructive bowel disorders & myasthenia gravis. Tramadol must not be used for withdrawal treatment.
Side-effects	Sweating, dizziness, nausea, vomiting, dry mouth and fatigue may occur after **MABRON** administration. It is also possible that the preparation may affect the cardiovascular system in rare cases. Undesirable effects occur particularly when the patient is under physical strain. Constipation, drowsiness, confusion, facial flushing, bradycardia, palpitations, orthostatic hypotension, hypothermia, restlessness, changes of mood, miosis, raised intracranial pressure.
Special Note	If the recommended dosage is considerably exceeded, which has occasionally occured during anaesthesia, the possibility of respiratory depression cannot be excluded. Note to road users: Even when taken 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 conjuction with alcohol.
Interaction with Other Drugs	On the concomitant administration of **MABRON** with substances which also act on the central nervous system (e.g. tranquillizers, hypnotics) the sedative effects (fatigue) may be intensified. At the same time, however, combining **MABRON** with a tranquillizer, for example, will probably have a favourable effect on pain sensation. **MABRON** should not be used in patients receiving MAO inhibitors.
Application and Dosage	The dosage should be adjusted to the intensity of the pain. Unless otherwise prescribed, **MABRON** should be administered as follows: **Single dose** for adults and adolescents over 14 years of age: i.v. 1 ampoule (100mg - injected slowly or diluted in solution for infusion and infused) i.m. 1ampoule (100mg) s.c. 1ampoule (100mg) In general the **daily dose** should not exceed 400mg Tramadol HCl (equivalent to 4 **MABRON** ampoules). In impaired renal or hepatic function it may be necessary to adjust the dose.
Duration of Treatment	During long-term treatment with **MABRON** the possibility of dependence cannot be entirely excluded. Therefore the physician is to decide on the duration of treatment and whether the preparation is to be withdrawn temporarily. **MABRON** should not be used longer than absolutely necessary from the therapeutic point of view.
Shelf-life	**MABRON** should not be used after the date of expiry indicated on the pack.
Information for the Patient	**MABRON** is a potent drug for the relief of pain, e.g. in wound pain, fractures, severe nerve pain, tumour pain, heart attack. It should not be used for minor pain. The effect sets in quickly and lasts for some hours.
Incompabilities	None known.