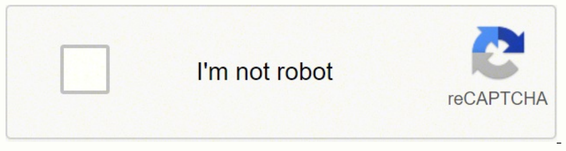

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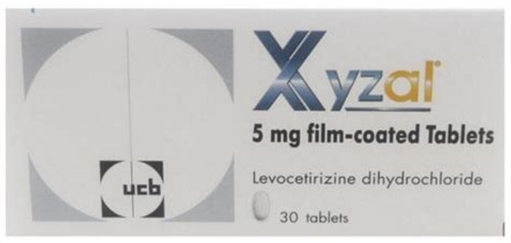
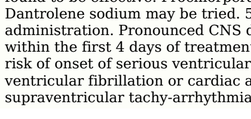
Prochlorperazine 5mg patient information leaflet





Reporting of suspected adverse reactions Reporting suspected adverse reactions after authorisation of the medicinal product is important. Possible adverse effects on the neonate include lethargy or paradoxical hyperexcitability, tremor and low apgar score. 4.6 Fertility, pregnancy and lactation Pregnancy Animal studies are insufficient with respect to reproductive toxicity. Some drugs interfere with absorption of neuroleptic agents: antacids, anti-Parkinson drugs and lithium. Insomnia and agitation may occur. 4.7 Effects on ability to drive and use machines Patients should be warned about drowsiness during the early days of treatment and advised not to drive or operate machinery 4.8 Undesirable effects Generally, adverse reactions occur at a low frequency; the most common reported adverse reactions are nervous system disorders. Endocrine disorders: Hyperprolactinaemia which may result in galactorrhoea, gynaecomastia, amenorrhoea and impotence. 4.2 Posology and method of administration Posology Adults Indication Dosage Prevention of nausea and vomiting 5 – 10 mg b.d. or t.d.s. Treatment of nausea and vomiting 20 mg stat, followed if necessary by 10 mg two hours later. For the full list of excipients, see section 6.1. 3 Pharmaceutical Form White to off-white, uncoated tablets. There are insufficient data to give a firm estimate of the precise magnitude of the risk and the cause of the increased risk is not known. Photosensitivity Because of the risk of photosensitisation, patients should be advised to avoid exposure to direct sunlight. Patients with an established diagnosis of diabetes mellitus or with risk factors for the development of diabetes who are started on Prochlorperazine tablets, should get appropriate glycaemic monitoring during treatment (see section 4.8). A premonitory sign may be sudden onset of fever after one to three weeks of treatment followed by the development of jaundice. If treatment is withdrawn, the recurrence of symptoms may not become apparent for some time. Skin and subcutaneous tissue disorders: Contact skin sensitisation may occur rarely in those frequently handling preparations of certain phenothiazines (see section 4.4). Anticholinergic agents may reduce the antipsychotic effects of neuroleptics and mild anticholinergic effect of neuroleptics may be enhanced by other anticholinergic drugs, possibly leading to constipation, heat stroke, etc. Tardive dyskinesia: If this occurs it is usually, but not necessarily, after prolonged or high dosage. The turnover of dopamine in the brain is increased. It allows continued monitoring of the benefit/risk balance of the medicinal product. There have been isolated reports of sudden death, with possible causes of cardiac origin (see section 4.4), as well as cases of unexplained sudden death, in patients receiving neuroleptic phenothiazines. The action of some drugs may be opposed by phenothiazine neuroleptics; these include amfetamine, levodopa, clonidine, guanethidine, adrenaline. The following schedule is suggested: Initially 12.5 mg twice daily for 7 days, the daily amount being subsequently increased 12.5 mg at 4 – 7 days interval until a satisfactory response is obtained. In patients treated concurrently with neuroleptics and lithium, there have been rare reports of neurotoxicity. It may also be used for schizophrenia (especially in the chronic stage), acute mania and as an adjunct to the short term management of anxiety. Treatment should be withheld on the development of jaundice (see section 4.4). Stroke In randomised clinical trials versus placebo performed in a population of elderly patients with dementia and treated with certain atypical antipsychotic drugs, a 3-fold increase of the risk of cerebrovascular events has been observed. The hypotensive effect of most antihypertensive drugs especially alpha adrenoceptor blocking agents may be exaggerated by neuroleptics. Depression As with all antipsychotic drugs, Prochlorperazine should not be used alone where depression is predominant. Prochlorperazine should be used with caution in patients with stroke risk factors. Withdrawal Acute withdrawal symptoms, including nausea, vomiting and insomnia, have very rarely been reported following the abrupt cessation of high doses of neuroleptics. If the patients is seen sufficiently soon (up to 6 hours) after ingestion of a toxic dose, gastric lavage may be attempted. Respiratory, thoracic and mediastinal disorders: Respiratory depression is possible in susceptible patients. One or more of the following may be seen: tremor, rigidity, akinesia or other features of Parkinsonism. 6 PHARMACEUTICAL PARTICULARS It is also extensively metabolised in the liver and is excreted in the urine and bile. Schizophrenia and other psychotic disorders Usual effective daily oral dosage is in the order of75 – 100 mg daily. The rate of metabolism and excretion decreases in old age. Peripheral vasoconstrictor agents are not generally recommended; avoid the use of adrenaline (epinephrine). Paediatric population Indication Dosage Prevention and treatment of nausea and vomiting If it is considered unavoidable to use Prochlorperazine for a child, the dosage is 0.25 mg/kg bodyweight two or three a day. Blood and lymphatic system disorders: A mild leukopenia occurs in up to 30% of patients on prolonged high dosage. Cases of venous thromboembolism, including cases of pulmonary embolism and cases of deep vein thrombosis have been reported with antipsychotic drugs – Frequency unknown Gastrointestinal disorders: Dry mouth may occur. Prochlorperazine has anti-emetic, anti-pruritic, serotonin-blocking, and weak antihistamine properties and slight ganglion-blocking activity. Skin reactions To prevent skin sensitisation in those frequently handling preparations of phenothiazines, the greatest care must be taken to avoid contact of the drug with the skin (see section 4.8). Paediatric population Prochlorperazine has been associated with dystonic reactions particularly after a cumulative dosage of 0.5 mg/kg. As agranulocytosis has been reported, regular monitoring of the complete blood count is recommended. Treatment is supportive. After some weeks at the effective dosage, an attempt should be made reduce this dosage. It is indicated in vertigo due to Meniere's syndrome, labyrinthitis and other causes, and for nausea and vomiting from any cause including that associated with migraine. In schizophrenia, the response to neuroleptic treatment may be delayed. There is no specific antidote. This could possibly happen with Prochlorperazine. Convulsions should be treated with iv diazepam. If the clinical situation permits, medical and laboratory evaluations (e.g. biochemical status and ECG) should be performed to rule out possible risk factors (e.g. cardiac disease; family history of QT prolongation; metabolic abnormalities such as hypokalaemia, hypocalcaemia or hypomagnesaemia; starvation; alcohol abuse; concomitant therapy with other drugs known to prolong the QT interval) before initiating treatment with Prochlorperazine and during the initial phase of treatment, or as deemed necessary during the treatment (see also sections 4.5 and 4.8). Avoid lidocaine and, as far as possible, long acting anti-arrhythmic drugs. If persistent or life threatening, appropriate anti-arrhythmic therapy may be considered. Breast-feeding Phenothiazines may be excreted in milk, therefore breast feeding should be suspended during treatment. Skin rashes of various kinds may also be seen in patients treated with the drug. 4.3 Contraindications Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. 4.4 Special warnings and precautions for use Prochlorperazine should be avoided in patients with liver or renal dysfunction, Parkinson's disease, hypothyroidism, cardiac failure, phaeochromocytoma, myasthenia gravis, prostate hypertrophy. Severe dystonic reactions usually respond to procyclidine (5-10mg) or orphenadrine (20-40mg) administered intramuscularly or intravenously. Neonates exposed to antipsychotics (including Prochlorperazine) during the third trimester of pregnancy are at risk of adverse reactions including extrapyramidal and/or withdrawal symptoms that may vary in severity and duration following delivery. Excipients with known effect: Each 5mg tablet contains 61.00mg lactose monohydrate. It should therefore be used cautiously in children Venous thromboembolism Cases of venous thromboembolism (VTE) have been reported with antipsychotic drugs. The occurrence of unexplained infections or fever may be evidence of blood dyscrasia (see section 4.8), and requires immediate haematological investigation. Prochlorperazine tablets are not licensed for the treatment of dementia-related behavioural disturbances. However, it may be combined with antidepressant therapy to treat those conditions in which depression and psychosis coexist. Neuroleptic jaundice has the biochemical and other characteristics of obstructive jaundice and is associated with obstruction of the canaliculi by bile thrombi; the frequent presence of an accompanying eosinophilia indicates the allergic nature of this phenomenon. Patients vary widely in response. White to off-white, circular, flat bevelled-edge uncoated tablets impressed “C” on one face and the identifying letters “Z and P” on either side of a central division line on the reverse. Salivary and gastric secretions are reduced. Consequently, newborns should be monitored carefully. Although neuroleptic malignant syndrome may be idiosyncratic in origin, dehydration and organic brain disease are predisposing factors. Adjunct in the short term management of anxiety 15 – 20 mg daily in divided doses initially but this may be increased if necessary to a maximum of 40 mg daily in divided doses. Pharmacological induction of emesis is unlikely to be of any use. The elderly are particularly susceptible to postural hypotension. Prochlorperazine may be metabolised by hydroxylation and conjugation with glucuronic acid, N-oxidation, oxidation of the sulfur atom and dealkylation. It inhibits dopamine and prolactin-release-inhibitory factor, thus stimulating the release of prolactin. Commonly just tremor. Intolerance to glucose, hyperglycaemia (see section 4.4) Pregnancy, puerperium and perinatal conditions: Drug withdrawal syndrome neonatal (see section 4.6) – Frequency not known. Where treatment for neuroleptic-induced extrapyramidal symptoms is required, anticholinergic antiparkinsonian agents should be used in preference to levodopa, since neuroleptics antagonise the antiparkinsonian action of dopaminergics. Its actions on the autonomic system produce vasodilatation, hypotension and tachycardia. Prochlorperazine is not recommended for children weighing less than 10 kg or below 1 year of age. The mechanism of such risk increase is not known. Hepatobiliary disorders: Jaundice, usually transient, occurs in a very small percentage of patients taking neuroleptics. Immune system disorders: Type I hypersensitivity reactions such as angioedema and urticaria. Activated charcoal should be given. Vascular disorders: Hypotension, usually postural, commonly occurs. Prochlorperazine should be used cautiously in the elderly owing to their susceptibility to drugs acting on the central nervous system and a lower initial dosage is recommended. Metabolism and nutrition disorders: Hyponatraemia Syndrome of inappropriate antidiuretic hormone secretion (SIADH). There is an increased risk of agranulocytosis when neuroleptics are used concurrently with drugs with myelosuppressive potential, such as carbamazepine or certain antibiotics and cytotoxics. Total daily amounts as small as 50 mg or even 25 mg have sometimes been found to be effective. Prochlorperazine is extensively bound to plasma proteins, widely distributed in the body (it crosses the blood/brain barrier) and its metabolites cross the placental barrier and are excreted in milk. It usually develops after weeks or months of treatment. Agranulocytosis may occur rarely: it is not dose related (see section 4.4). Dantrolene sodium may be tried. 5 PHARMACOLOGICAL PROPERTIES 5.1 Pharmacodynamic properties Pharmacotherapeutic group: Phenothiazines with piperazine structure Prochlorperazine maleate is a phenothiazine. Relapse may also occur, and the emergence of extrapyramidal reactions has been reported. Method of Administration For oral administration. Pronounced CNS depression requires airway maintenance or, in extreme circumstances, assisted respiration. Elderly A lower dose is recommended (see section 4.4). Nervous system disorders: Acute dystonia or dyskinesias, including oculogyric crisis, usually transitory are commoner in children and young adults, and usually occur within the first 4 days of treatment or after dosage increases. Severe extrapyramidal dyskinesias may occur. Data from epidemiological studies do not suggest a risk of congenital malformations in children exposed in utero to Prochlorperazine. QT prolongation Neuroleptic phenothiazines may potentiate QT interval prolongation which increases the risk of onset of serious ventricular arrhythmias of the torsade de pointes type, which is potentially fatal (sudden death). Prochlorperazine has sedative properties but tolerance to the sedation usually develops rapidly. Cardiac arrhythmias, including ventricular arrhythmias and atrial arrhythmias, A-V block, ventricular tachycardia, which may result in ventricular fibrillation or cardiac arrest have been reported during neuroleptic phenothiazine therapy, possibly related to dosage. Parkinsonism is more common in adults and the elderly. Dosage should therefore be kept low whenever possible. There is inadequate evidence of safety in pregnancy. Respiratory depression may occur. Ventricular or supraventricular tachy-arrhythmias usually respond to restoration of normal body temperature and correction of circulatory or metabolic disturbances. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme; website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play

or Apple App Store. It can even occur after treatment has been stopped. Since patients treated with antipsychotics often present with acquired risk factors for VTE, all possible risk factors for VTE should be identified before and during treatment with Prochlorperazine and preventative measures undertaken. As a precautionary measure, Prochlorperazine should be avoided during pregnancy unless the potential benefits outweigh the potential risks. The risk-benefit should be fully assessed before Prochlorperazine treatment is commenced. Patients on high dosage should be warned that they may develop photosensitivity in sunny weather and should avoid exposure to direct sunlight. ATC code: NO5A B04 Prochlorperazine has a wide range of activity arising from its depressant actions on the CNS and its alpha-adrenergic blocking and weaker anti-muscarinic properties. Cardiac disorders: ECG changes include QT prolongation (as with other neuroleptics), ST depression, U-Wave and T-Wave changes. Akathisia characteristically occurs after large initial doses. Close monitoring is required in patients with epilepsy or a history of seizures, as phenothiazines may lower the seizure threshold. 5.2 Pharmacokinetic properties Prochlorperazine is well absorbed from the GI tract but is subject to considerable first pass metabolism from the gut wall. Pre-existing cardiac disease, old age, hypokalaemia and concurrent tricyclic antidepressants may predispose. Neuroleptics may occasionally prolong labour and at such time should be withheld until the cervix is dilated 3 – 4 cm. Patients with rare hereditary problems of galactose intolerance, the total lactase deficiency or glucose-galactose malabsorption should not take this medicine, as it contains lactose. Care should also be taken not to confuse the adverse effects of Prochlorperazine, e.g. orthostatic hypotension, with the effects due to the underlying disorder. (See section 4.9). It inhibits the heat regulating centre, can relax smooth muscle and has membrane stabilising and hence local anaesthetic properties. Therefore, gradual withdrawal is advisable. High doses of neuroleptics reduce the response to hypoglycaemic agents, the dosage of which might have to be raised. However, potential harmful effect in animals cannot be ruled out. QT prolongation is exacerbated, in particular, in the presence of bradycardia, hypokalaemia, and congenital or acquired (i.e. drug induced) QT prolongation. Elderly It should be used with caution in the elderly, particularly during very hot or very cold weather (risk of hyper-, hypothermia). Avoid concomitant treatment with other neuroleptics (see section 4.5). Positive inotropic agents such as dopamine may be tried if fluid replacement is insufficient to correct the circulatory collapse. Vertigo and Meniere's syndrome 5 mg t.d.s. increasing if necessary to a total of 30 mg daily. There is an increased risk of drug-induced Parkinsonism in the elderly particularly after prolonged use. General disorders and administration site conditions: Neuroleptic malignant syndrome (hyperthermia, rigidity, autonomic dysfunction and altered consciousness) may occur with any neuroleptic (see section 4.4). Increased mortality in elderly people with dementia Data from two large observational studies showed that elderly people with dementia who are treated with antipsychotics are at a small increased risk of death compared with those who are not treated. Neuroleptic malignant syndrome should be treated with cooling. Plasma half-life is reported to be only a few hours but elimination of the metabolites may be very prolonged. Hyperglycaemia Hyperglycaemia or intolerance to glucose has been reported in patients treated with antipsychotic phenothiazines. Increases or decreases in the plasma concentrations of a number of drugs, e.g. propranolol, phenobarbital have been observed but were not of clinical significance. Eye disorders: Ocular changes and the development of metallic greyish-mauve coloration of exposed skin have been noted in some individuals mainly females, who have received chlorpromazine continuously for long periods (four to eight years). It should be avoided in patients known to be hypersensitive to phenothiazines or with a history of narrow angle glaucoma or agranulocytosis. 5.3. Preclinical Safety Data Not applicable. Elderly or volume depleted subjects are particularly susceptible; it is more likely to occur after intramuscular injection. 4 CLINICAL PARTICULARS 4.1 Therapeutic indications Prochlorperazine is a potent phenothiazine neuroleptic. There is evidence that the antagonism of central dopaminergic function is related to the therapeutic effect in psychotic conditions. The CNS depressant actions of neuroleptic agents may be intensified (additively) by alcohol, barbiturates and other sedatives. Nasal stuffiness may occur. After several weeks dosage may be reduced gradually to 5 – 10 mg daily. An increase in the risk with other antipsychotic drugs or other populations of patients cannot be excluded. Signs of autonomic dysfunction, such as sweating and arterial instability, may precede the onset of hyperthermia and serve as early warning signs. 4.5 Interaction with other medicinal products and other forms of interaction Adrenaline must not be used in patients who have overdosed with prochlorperazine maleate. Generalised vasodilatation may result in circulatory collapse; raising the patient's legs may suffice, in severe cases, volume expansion by iv fluids may be needed; infusion fluids should be warmed before administration in order not to aggravate hypothermia. SUMMARY OF PRODUCT CHARACTERISTICS 1 NAME OF THE MEDICINAL PRODUCT Prochlorperazine tablets BP 5mg 2 QUALITATIVE AND QUANTITATIVE COMPOSITION Each tablet contains 5mg Prochlorperazine Maleate PhEur. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, or feeding disorder. Neuroleptic malignant syndrome It is imperative that treatment be discontinued in the event of unexplained fever, as this may be a sign of neuroleptic malignant syndrome (pallor, hyperthermia, autonomic dysfunction, altered consciousness, muscle rigidity). Plasma concentrations following oral administration are much lower than those following intramuscular injection, and are subject to wide inter-subject variation. Simultaneous administration of desferrioxamine and prochlorperazine has been observed to induce transient metabolic encephalopathy characterised by loss of consciousness for 48 – 72 hours. Convulsions. There is no simple correlation between plasma concentrations of prochlorperazine and its metabolites, and therapeutic effect. There is an increased risk of arrhythmias when neuroleptics are used with concomitant QT prolonging drugs (including certain antiarrhythmics, antidepressants and other antipsychotics) and drugs causing electrolyte imbalance. 4.9 Overdose Symptoms of phenothiazine overdosage include drowsiness or loss of consciousness, hypotension, tachycardia, ECG changes, ventricular arrhythmias and hypothermia.

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