ONDANSETRON MEDIS 4 mg – 8 mg

Ondansetron

FORMS AND PRESENTATIONS :
• Injectable solutions :
ONDANSETRON MédiS® 4 mg / 2 ml - Ondansetron 2 mg/ml : injectable solution (I.V.) – Box of 5 ampoules of 2 ml.
ONDANSETRON MédiS® 8 mg / 4 ml - Ondansetron 2 mg/ml : injectable solution (I.V.) – Box of 5 ampoules of 4 ml.
• Oral forms :
ONDANSETRON MédiS® 4 mg - Ondansetron 4 mg - yellow coated tablet : Box of 10 tablets.
ONDANSETRON MédiS® 8 mg - Ondansetron 8 mg - orange coated tablet : Box of 10 tablets.
COMPOSITION :
• Injectable solutions :

	ONDANSETRON MédiS® 4 mg / 2 ml	**ONDANSETRON MédiS® 8 mg / 4 ml**
Ondansetron (DCI) hydrochloride dehydrate as Ondansetron	4 mg	8 mg
Excipients : Sodium chloride ..... Citric acid monohydrate, sodium citrate ..... W.F.I.	 18 mg s.q. s.q.f 2 ml	 36 mg s.q. s.q.f 4 ml

Oral tablets :

	ONDANSETRON MédiS® 4 mg	**ONDANSETRON MédiS® 8 mg**
Ondansetron (as hydrochloride dihydrate)	4 mg (5 mg)	8 mg (10 mg)
Excipients :	Lactose monohydrate, microcristalline cellulose, Starch 1500, magnesium stearate and Opadry ..... s.q.f.one tablet	
List of active excipients : : Lactose monohydrate		

THERAPEUTIC INDICATIONS:
• Injectable solutions:
- Prevention and treatment of nauseas and acute vomiting induced by cytotoxic chemotherapy and the radiotherapy in the adult.
- Prevention of nauseas and acute vomiting induced by cytotoxic chemotherapy in the child.
- Treatment of nauseas and vomiting postoperative in the adult and the child.

• Oral forms:
- Prevention of nauseas and acute vomiting induced by cytotoxic chemotherapy in the adult.
- Prevention and treatment of nauseas and delayed vomiting induced by cytotoxic chemotherapy in the adult and the child.
- Prevention and treatment of nauseas and vomiting acute and delayed induced by the radiotherapy in the adult.

POSOLOGY AND MODE OF ADMINISTRATION:
Posology:
Adult older than 15 years:
Nausea and vomiting induced by chemotherapy:
Initial dose is usually 8 mg by slow IV administration, 30 minutes before chemotherapy or radiotherapy or by oral form tablets.
Prevention and treatment of nauseas or vomiting delayed:
The dose of 8 mg is administered every 12 hours by oral route, over one average duration from 2 to 3 days being able to go up to 5 days. In certain circumstances, an association with a corticotherapy per bone could
be prescribed.
Post operative nausea and vomiting:
4 mg on slow IV administration.
Children older than 2 years:
Nausea and vomiting induced by chemotherapy:
Initial dose is usually 5 mg/m2 by slow IV administration, before chemotherapy.
For the prevention and the treatment of nauseas and vomiting induced by the cytotoxic treatments: the dose is 4 mg by oral route (child from 10 to 15 kg) or 8 mg if 25 kg to renew if necessary all the 12H on a 5 days maximum.
Post operative nausea and vomiting:
Initial dose is usually 0.1 mg/kg by slow IV administration until a maximal dose of 4mg.
Olders:
The efficiency and tolerance of the drug are similar in young and older patients, more than 65 years.
Hepatic insufficiency:
Do not use more than a total daily dose of 8 mg.
Mode of administration:
Slow intravenous injection or perfusion.
Oral route.
CONTRAINDICATIONS:
Allergic to any component of the drug.
WARNING AND PRECAUTIONS OF USE:
Warning:
Cardiovascular check-up must be done when thoracic pain, syncope, or cardiac arrhythmia are noted.
Be aware when hypersensitivity reactions to another 5HT3 antagonist are noted.
Precautions of use:
Be aware in salt and water restriction diet patients because of 9 mg sodium chloride per millilitre container of the drug.
In hepatic insufficiency, Ondonsetron pharmacokinetic parameters are modified: reduction of total plasmatic clearance and increase of plasmatic half- life.
Pregnancy and nursing:
It would be better to ovoid use ondansetron in pregnancy women and in case of nursing.
ADVERSES EFFECTS:
These adverse effects can be seen : headache, hot flush, hiccups, biological hepatic anomalies, constipation, hypotension, thoracic pain, arrhythmia and bradycardia, extra pyramidal reaction such as ocular crisis or convulsion, immediate allergic reaction, transitory visual trouble and dizziness, in rapid IV injection, some local reactions can be seen (erythematic, urticare, prurit, pain) and in rare case vena infection.
OVERDOSAGE:
There is no antidote to Ondansetron. Consequently, in overdose, symptomatic supply is the only treatment
INCOMPATIBILITIES:
Ondansetron Médis, injectable solution is incompatible with bicarbonate solutions.
It must be administered only with recommended solutions (isotonic sodium chloride; Ringer Lactate; isotonic Glucose solution)
STORAGE CONDITIONS:
To store at temperature under 25 °C and keep away from light in the original packaging.
DELIVERY CONDITIONS:
Liste I, only under medical prescription.
PRESENTATIONS :

Specialities	**Presentations**	**M.A. number**
ONDANSETRON MédiS® 4 mg / 2 ml	Box of 05 ampoules of 2 ml	923 333 2H
ONDANSETRON MédiS® 8 mg / 4 ml	Box of 05 ampoules of 4 ml	923 333 1H
ONDANSETRON MédiS® 4 mg	Box of 10 tablets	923 333 3
ONDANSETRON MédiS® 8 mg	Box of 10 tablets	923 333 4

DATE OF THE LAST REVISION : July 2015

This is a drug

- A drug is a specific product agent.
- A drug is a product acting on your health and its use, contrary to prescriptions may be dangerous for you.
- Strictly respect the doctor's prescription and the instructions of use he has prescribed.
- Follow your pharmacist's know this drug ; its indications and contra-indications.
- Do not discontinue the drug intake by yourself during the prescription period.
- Do not repeat the prescription or increase the dosage without consulting your doctor.

KEEP ANY DRUG OUT OF THE REACH OF CHILDREN.

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MédiS

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