SCHEDULING STATUS:
S4

PROPRIETARY NAME AND DOSAGE FORM:
ONDANSETRON 4 mg/2 ml BIOTECH
ONDANSETRON 8 mg/4 ml BIOTECH

COMPOSITION:
ONDANSETRON 4 mg/2 ml BIOTECH:
Each 2 ml ampoule contains ondansetron 4 mg (as hydrochloride dihydrate) for intramuscular or intravenous administration.
ONDANSETRON 8 mg/4 ml BIOTECH:
Each 4 ml ampoule contains ondansetron 8 mg (as hydrochloride dihydrate) for intramuscular or intravenous administration.

PHARMACOLOGICAL CLASSIFICATION:
A.5.10 Medicines affecting autonomic functions. Serotonin antagonists.

PHARMACOLOGICAL ACTION:
Ondansetron is a potent, highly selective 5-HT_3 receptor-antagonist.
Ondansetron's actual mechanism of action in the control of nausea and vomiting is unknown. Chemotherapeutic agents and radiotherapy may cause release of 5-HT in the small intestine initiating a vomiting reflex by activating vagal afferents via 5-HT_3 receptors. The initiation of this reflex is blocked by ondansetron. Activation of vagal afferents may also cause a release of 5-HT in the area postrema, located on the floor of the fourth ventricle, and this may also promote emesis through a central mechanism.
Thus, the effect of ondansetron in the management of the nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy is due to the antagonism of 5-HT_3 receptors on neurons located both in the peripheral and central nervous system. In psychomotor testing, ondansetron does not cause sedation nor impair performance.
Pharmacokinetics
Plasma prolactin concentrations are not altered by ondansetron. Ondansetron is rapidly absorbed following oral administration, with maximum plasma concentrations of about 30 ng /ml being attained approximately 1,6 hours after an 8 mg dose. The absolute oral bioavailability of the drug is approximately 60 %. The disposition of ondansetron following both intravenous and oral dosing is similar with a terminal elimination half-life of about 3 hours and a steady-state volume of distribution of about 140 L. Plasma protein binding is 70-76 %. Ondansetron is cleared from the systemic circulation predominantly by metabolism with less than 5 % of a dose excreted unchanged in the urine.
Studies in healthy elderly volunteers have shown a prolonged elimination half-life (5 hrs) and slightly increased bioavailability (65 %) for ondansetron.
As a result of reduced pre-systemic metabolism in patients with severe hepatic impairment, the systemic clearance of ondansetron is markedly reduced with prolonged elimination half – lives (15 – 32 hrs) and an oral bioavailability approaching 100 %.

INDICATIONS:
ONDANSETRON BIOTECH is indicated for the management of nausea and vomiting induced by cytotoxic chemotherapy and radiotherapy.
ONDANSETRON BIOTECH is also indicated for the prevention and treatment of post-operative nausea and vomiting. Routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and vomiting will occur.

CONTRAINDICATIONS:
ONDANSETRON BIOTECH is contraindicated in patients known to have hypersensitivity to ondansetron or any of the ingredients of the preparation.
The use of ONDANSETRON BIOTECH for post-operative nausea and vomiting is contra-indicated in pregnancy.

WARNINGS:
Patients with hepatic impairment:
In patients with moderate or severe impairment of hepatic function, clearance of ondansetron is significantly reduced and serum half-life significantly prolonged.
In such patients, a total daily dose of 8 mg should not be exceeded.

PREGNANCY AND LACTATION:
Pregnancy: Safety in pregnancy has not been established.
Lactation: Tests have shown that ondansetron passes into the milk of lactating animals.
It is therefore recommended that mothers receiving ONDANSETRON BIOTECH should not breast feed their babies.

DOSAGE AND DIRECTIONS FOR USE:
Chemotherapy and radiotherapy induced nausea and vomiting
The emetogenic potential of cancer treatment varies according to the doses and combinations of chemotherapy and radiotherapy regimens used.
Adults:
Emetogenic chemotherapy and radiotherapy:
For most patients receiving emetogenic chemotherapy or radiotherapy, ONDANSETRON 8 mg/4 ml BIOTECH should be administered as a slow IV or IM injection immediately before treatment, or orally (film-coated tablets) 1 - 2 hours before treatment, followed by 8 mg orally twelve hourly.
In circumstances where delayed or prolonged emesis is expected after the first 24 hours, ondansetron may be continued orally, 8 mg twice daily for up to five days after a course of treatment.
Highly Emetogenic Chemotherapy:
A single dose of ONDANSETRON 8 mg/4 ml BIOTECH by slow IV or IM injection immediately before chemotherapy has been shown to be effective in many patients.
Higher doses may be required in some patients, particularly those on high dose cisplatin, and the doses should be adjusted according to the severity of the emetogenic challenge.
In these patients the following dose schedules have been shown to be effective:
A dose of 8 mg by slow IV or IM injection immediately before chemotherapy, followed by two further IV or IM doses of 8 mg two to four hours apart, or by a constant infusion of 1 mg/hour for up to 24 hours.
OR
A single dose of 32 mg diluted in 50-100 ml of saline or other compatible infusion fluid, infused over not less than 15 minutes immediately before chemotherapy.
The efficacy of ONDANSETRON BIOTECH in highly emetogenic chemotherapy may be enhanced by the addition of a single intravenous dose of dexamethasone phosphate 20 mg administered 30-45 minutes prior to the first ONDANSETRON BIOTECH dose prior to chemotherapy.
To protect against delayed or prolonged emesis after the first 24 hours, ondansetron may be continued orally, 8 mg twice daily for up to 5 days after a course of treatment.
Children:
Experience is currently limited, but ondansetron was effective and well tolerated in children over the age of 4 years, when given intravenously at a dose of 5 mg/m^2 over 15 minutes, immediately before chemotherapy, followed by oral therapy of doses of ondansetron 4 mg every 12 hours for up to 5 days.
For prevention of post-operative nausea and vomiting in paediatric patients two years and older having surgery performed under general anaesthesia, ONDANSETRON BIOTECH may be administered by slow intravenous injection at a dose of 0,1 mg/kg up to a maximum of 4 mg either prior to, at or after induction of anaesthesia.
For the treatment of established post-operative nausea and vomiting in paediatric patients two years and older, ONDANSETRON BIOTECH may be administered by slow intravenous injection at a dose of 0,1 mg/kg up to maximum of 4 mg.
Repeat dosing for paediatric patients who continue to experience nausea and/or vomiting has not been studied, and should thus not been given.
Elderly patients:
Efficacy and tolerance in patients aged over 65 years was similar to that seen in younger adults indicating no need to alter dosage or route of administration in the elderly.
Prevention and treatment of post-operative nausea and vomiting
Adults:
Immediately before induction of anaesthesia, or post-operatively if the patient experiences nausea and/or vomiting occurring shortly after surgery, administer 4 mg undiluted intramuscularly or intravenously. If given intravenously, it must be administered in not less than 30 seconds, preferable over 2-5 minutes.
Alternatively, for the prevention of post-operative nausea and vomiting, 16 mg may be given orally (film-coated tablets) one hour prior to induction of anaesthesia.
Repeat dosing for patients who continue to experience nausea and/or vomiting post-operatively has not been studied. While recommended as a fixed dose for all, few patients above 80 kg or below 40 kg have been studied.
Children:
For prevention of post-operative nausea and vomiting in paediatric patients two years and older having surgery performed under general anaesthesia, ONDANSETRON BIOTECH may be administered by slow intravenous injection at a dose of 0,1 mg/kg up to a maximum of 4 mg either prior to, at or after induction of anaesthesia.
For the treatment of established post-operative nausea and vomiting in paediatric patients two years and older, ONDANSETRON BIOTECH may be administered by slow intravenous injection at a dose of 0,1 mg/kg up to maximum of 4 mg.
Repeat dosing for paediatric patients who continue to experience nausea and/or vomiting has not been studied, and should thus not been given.
Elderly:
Safety and efficacy have not been established in the use of ONDANSETRON BIOTECH in the prevention and treatment of post-operative nausea and vomiting in the elderly.
Patients with renal/hepatic impairment:
Patients with renal impairment: No alteration of daily dosage or frequency of dosing, or route of administration is required. There is limited information available on severely impaired renal or hepatic impairment.
Patients with hepatic impairment: Clearance of ONDANSETRON BIOTECH is significantly reduced and serum half-life significantly prolonged in patients with moderate or severe impairment of hepatic function. In such patients, a total daily dose of 8 mg should not be exceeded.
ONDANSETRON BIOTECH injection should not be administered in the same syringe or infusion as any other medication.
ONDANSETRON BIOTECH injection ampoules should not be autoclaved.
Compatibility with intravenous fluids
ONDANSETRON BIOTECH injection should only be admixed with those infusion solutions which are recommended.
Intravenous solutions should be prepared at the time of infusion.
ONDANSETRON BIOTECH injection has been shown to be stable for seven days at room temperature under fluorescent lighting or in a refrigerator with the following intravenous infusion fluids:
5% glucose solution; 0.9% sodium chloride solution; 10% mannitol solution or Ringers solution.
Compatibility studies have been undertaken in polyethylene bags and in clear glass vials.
It is considered that ONDANSETRON BIOTECH injection diluted with other compatible infusion fluids would be stable in polypropylene syringes.
NOTE: Preparation must be under the appropriate aseptic conditions if extended storage periods are required.
Compatibility with other medicines
NOTE: It is not recommended to mix medicines for infusion.
ONDANSETRON BIOTECH injection may be administered by intravenous infusion at 1 mg/hour, e.g. from an infusion bag, or syringe pump. The following medicines may be administered via the Y-site of the ONDANSETRON BIOTECH giving set for ondansetron concentrations of 16 to 160 micrograms/ml (e.g. 8 mg/500 ml and 8 mg/50 ml respectively).
Cisplatin: Concentrations up to 0,48 mg/ml (e.g. 240 mg in 500 ml) administered over one to eight hours.
Dexamethasone: Dexamethasone sodium phosphate 20 mg may be administered as a slow intravenous injection over 2-5 minutes via the Y-site of an infusion set delivering 8 mg of ONDANSETRON BIOTECH diluted in 50-100 ml of a compatible infusion fluid over approximately 15 minutes. Compatibility between dexamethasone sodium phosphate and ONDANSETRON BIOTECH has been demonstrated supporting administration of these drugs through the same giving set, with resulting in-line concentrations in the ranges of 32 µg - 2,5 mg/ml for dexamethasone sodium phosphate and 8 µg - 1 mg/ml for ONDANSETRON BIOTECH.
5-Fluorouracil: Concentrations up to 0,8 mg/ml (e.g. 2,4 g in 3 litres, or 400 mg in 500 ml) administered at a rate of at least 20 ml per hour (500 ml per 24 hours). Higher concentrations of 5-fluorouracil infusion may contain up to 0,045 % m/v magnesium chloride in addition to other excipients shown to be compatible.
Carboplatin: Concentrations in the range 0,18 mg/ml to 9,9 mg/ml (e.g. 90 mg in 500 ml to 990 mg in 100 ml), administered over 10 minutes to one hour.
Etoposide: Concentrations in the range 0,14 mg/ml to 0, 25 mg/ml (e.g. 72 mg in 500 ml to 250 mg in 1 litre), administered over thirty minutes to one hour.
Ceftazidime: Doses in the range 250 mg to 2000 mg reconstituted with Water for Injection BP, as recommended by the manufacturer (e.g. 2,5 ml for 250 mg and 10 ml for 2 g ceftazidime), and given as an intravenous bolus injection over approximately five minutes.
Cyclophoshamide: Doses in the range 100 mg to 1 g, reconstituted with Water for Injection BP, 5 ml per 100 mg cyclophosphamide, as recommended by the manufacturer, and given as an intravenous bolus injection over approximately five minutes.
Doxorubicin: Doses in the range 10 to 100 mg, reconstituted with Water for Injection BP, 5 ml per 10 mg doxorubicin, as recommended by the manufacturer, and given as an intravenous bolus injection over approximately five minutes.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:
The following side-effects can occur:
Central Nervous System
Headache. Seizures have been observed rarely.
Cardiovascular System
Arrhythmias, hypotension, bradycardia and chest pain have been rarely reported.
Gastrointestinal System
Increase in large bowl transit time is known to be caused by ondansetron which may cause constipation in some patients.
Hypersensitivity reactions
Immediate hypersensitivity reactions, sometimes severe (e.g. anaphylaxis, bronchospasm, shortness of breath, hypotension, shock, angioedema, urticaria) have been reported.
Musculoskeletal
There have been rare reports of involuntary movement disorders without efinitive evidence of persistent clinical sequelae.
Local reactions
Pain, redness and burning at site of injection.
Other
A sensation of warmth or flushing, hiccups and transient, asymptomatic increases in aminotransferases.
Dizziness and transient visual disturbances (e.g. blurred vision) have been reported during or shortly after rapid intravenous administration of ONDANSETRON BIOTECH.
Special precautions:
Hypersensitivity reactions have been reported in patients who have exhibited hypersensitivity to other selective 5-HT_3 receptor antagonists. Patients with signs of subacute intestinal obstructions should be monitored following administration, as ondansetron is known to increase large bowl transit time.
As this product contains aspartame, caution is advised in patients with phenylketonuria.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
See SIDE-EFFECTS AND SPECIAL PRECAUTIONS. Manifestations that have been reported include severe constipation, visual disturbances, hypotension and a vasovagal episode with transient second degree AV block. In cases of suspected overdose, symptomatic and supportive therapy should be given as appropriate, as there is no specific antidote for ondansetron.

IDENTIFICATION:
ONDANSETRON 4 mg/2 ml BIOTECH: A clear, colourless solution, practically free from visible particles.
ONDANSETRON 8 mg/4 ml BIOTECH: A clear, colourless solution, practically free from visible particles.

PRESENTATION:
ONDANSETRON 4 mg/2 ml BIOTECH: 2 ml clear glass ampoules (5 ampoules packed into a carton).
ONDANSETRON 8 mg/4 ml BIOTECH: 4 ml clear glass ampoules (5 ampoules packed into a carton).

STORAGE INSTRUCTIONS:
Store at or below 25°C. Protect from light.
KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBERS:
ONDANSETRON 4 mg/2 ml BIOTECH: 38/5.10/0200
ONDANSETRON 8 mg/4 ml BIOTECH: 38/5.10/0217

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Biotech Laboratories (Pty) Ltd.
Ground Floor, Block K West, Central Park
400 16th Road, Randjespark, Midrand,1685,
South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
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SKEDULERING STATUS:
S4

HANDELSNAAM EN DOSERING VORM:
ONDANSETRON 4 mg/ 2 ml BIOTECH
ONDANSETRON 8 mg/ 4 ml BIOTECH

SAMESTELLING:
ONDANSETRON 4 mg/ 2 ml BIOTECH:
Elke 2 ml ampule bevat ondansetron 4 mg (as hidrokloried dihidraat) vir binnespierse of binneaarse-toediening.
ONDANSETRON 8 mg/4 ml BIOTECH:
Elke 4 ml ampule bevat ondansetron 8 mg (as hidrokloried dihidraat) vir binnespierse of binneaarse- toediening.

FARMAKOLOGIESE KLASSIFIKASIE:
A.5.10 Medisyne wat outonome funksies beïnvloed. Serotonien antagoniste.

FARMAKOLOGIESE AKSIE:
Ondansetron is 'n potente hoogs selektiewe 5-HT_3 reseptor-antagonis.
Ondansetron se werklike meganisme van aksie in die beheer van naarheid en braking is onbekend. Chemoterapeutiese middels en radioterapie kan lei tot die vrystelling van 5-HT in die dunderm, wat 'n braak reflex kan inisiëer deur aktivering van die vagale afferente via die 5-HT_3 reseptore. Die aktivering van hierdie reflex word deur ondansetron geblokkeer. Aktivering van vagale afferente mag ook die vrystelling van 5-HT in die area postrema, wat op die vloer van die vierde ventrikel geleë is, veroorsaak. Dit kan ook emese deur 'n sentrale meganisme bevorder.
Dus, die effek van ondansetron in die behandeling van naarheid en braking veroorsaak deur sitotoksiese chemoterapie en radioterapie is die gevolg van antagonisme van 5-HT_3 reseptore op die neurons wat in beide die perifêre en sentrale senuwee sisteem geleë is. Tydens psigomotoriese toetsing, het ondansetron nie sedasie veroorsaak of optrede benadeel nie.
Farmakokinetika:
Plasma prolaktien konsentrasies word nie verander deur ondansetron nie.
Ondansetron word vinnig geabsorbeer na mondelingse toediening, met maksimum plasma konsentrasies van ongeveer 30 ng /ml wat bereik word nagenoeg 1,6 uur na toediening van 8 mg dosering. Die absolute orale biobeskikbaarheid van die middel is ongeveer 60 %. Die verspreiding van ondansetron na beide binneaarse of orale dosering is soortgelyk aan 'n terminale eliminasie halfleeftyd van ongeveer 3 ure en 'n bestendige-staat volume van verspreiding van ongeveer 140L. Plasma proteïen-binding is 70-76%. Ondansetron word afgebreek deur sistemiese sirkulasie hoofsaaklik deur metabolisme, met minder as 5% wat onveranderd in die urine uitgeskei word.
Studies in gesonde volwasse vrywilligers het 'n verlengde eliminasie halfleeftyd (5 ure) en matig verhoogde biobeskikbaarheid (65%) van ondansetron getoon.
As gevolge van die verminderde pre-sistemiese metabolisme in pasiënte met erge lewer-inperking, word die sistemiese uitskeiding van ondansetron merkbaar verminder met 'n verlengde eliminasie halfleeftyd (15-32 ure) en orale biobeskikbaarheid nader aan 100%.

INDIKASIES:
ONDANSETRON BIOTECH word aangedui vir die behandeling van naarheid en braking veroorsaak deur sitotoksiese chemoterapie en radioterapie.
ONDANSETRON BIOTECH word ook aangedui vir die voorkoming en behandeling van post-operatiewe naarheid en braking. Roetine-profilakse word nie aanbeveel in pasiënte waar naarheid en braking onwaarskynlik is nie.

KONTRAÏNDIKASIES:
ONDANSETRON BIOTECH is teenaangedui in pasiënte wat bekende hipersensitiwiteit teenoor ondansetron of enige van die ander bestanddele van die middel het. Die gebruik van ONDANSETRON BIOTECH vir post-operatiewe naarheid en braking is teenaangedui tydens swangerskap.

WAARSKUWINGS:
Pasiënte met hepatiese inperking:
In pasiënte met matige of erge inperking van hepatiese funksie, word uitskeiding van ondansetron merkbaar verminder en die serum halfleeftyd merkbaar verleng. In hierdie pasiënte moet 'n daaglikse dosering van 8 mg nie oorskry word nie.

SWANGERSKAP EN LAKTASIE:
Swangerskap: Veiligheid gedurende swangerskap is nie vasgestel nie.
Laktasie: Toetse het getoon dat ondansetron in borsmelk uitgeskei word.
Dit word daarom aanbeveel dat moeders wat hul babas borsvoed nie ONDANSETRON BIOTECH ontvang nie.

DOSERING EN GEBRUIKSAANWYSINGS:
Naarheid en braking veroorsaak deur chemoterapie en radioterapie:
Die emetogeniese potensiaal van kankerbehandeling wissel afhangend van die dosering en kombinasies van chemoterapie en radioterapie regimente wat gebruik word.
Volwassenes:
Emetogeniese chemotherapie en radioterapie:
By meeste pasiënte wat emetogeniese chemoterapie of radioterapie ontvang, moet ONDANSETRON 8 BIOTECH stadig as binneaarse (IV) of binnespierse (IM) inspuiting toegedien word, onmiddellik voor behandeling, of mondelings (film-bedekte tablette) 2 ure voor behandeling, gevolg deur 8 mg mondelings elke 12 ure.
Onder omstandighede waar vertraagde of verlengde emese verwag word na die eerste 24 uur, moet ondansetron mondelings voortgesit word, 8 mg twee keer per dag vir tot vyf dae na 'n kursus van behandeling.
Hoogs Emetogene Chemoterapie:
'n Enkele dosering van ONDANSETRON 8 mg/4 ml BIOTECH deur stadige binneaarse(IV) of binnespierse-inspuiting(IM), onmiddellik voor chemoterapie, is effektief vir die meerderheid van pasiënte.
Hoër dosisse mag benodig word in sommige pasiënte, veral die op hoë doserings van Sisplatien. Die dosering moet ook aangepas word volgens die ernstigheid van die emetogene uitdaging.
Die volgende dosering skedule was effektief vir hierdie pasiënte:
'n Dosis van 8 mg deur middel van stadige binneaarse(IV) of binnespierse-inspuiting(IM) onmiddellik voor chemoterapie, gevolg deur twee verdere IV of IM doserings van 8 mg twee tot vier ure uitmekaar, of teen 'n reëlmatige infusie van 1 mg/uur vir soveel as 24 uur.
OF
'n Enkele dosis 32 mg verdun in 50 – 100 ml soutoplossing of ander aanvaarbare infusie vloeistof, toegedien nie minder as 15 minute voor chemoterapie nie.
Die effektiwiteit van ONDANSETRON BIOTECH in hoogs emetogene chemoterapie kan versterk word deur die toevoeging van 'n enkele binneaarse dosis van deksametasoon fosfaat 20 mg, toegedien 30 – 45 minute voor die eerste ONDANSETRON BIOTECH dosering net voor chemoterapie.
Ten einde vertraagde of verlengde emese te voorkom na die eerste 24 uur, kan ondansetron volgehou word, met mondelingse dosisse van 8 mg twee maal per dag vir tot 5 dae na afloop van 'n behandelingskursus.
Kinders:
Ondervinding is tans beperk, maar ondansetron was effektief en goed verdra in kinders oor die ouderdom van 4 jaar, wanneer binneaars gegee is teen 'n dosis van 5 mg/m^2 oor 15 minute, onmiddellik voor chemoterapie, gevolge deur mondelingse behandeling met 'n dosis van 4 mg elke 12 ure vir tot 5 dae.
Vir die voorkoming van post-operatiewe naarheid en braking in pediatriese pasiënte van twee jaar en ouer, wat sjirurgie onder algemene narkose ondergaan, kan ONDANSETRON BIOTECH toegedien word deur 'n stadige binneaarse-inspuiting met dosering van 0,1 mg/kg tot 'n maksimum van 4 mg net voor en net na narkose induksie.
Vir die behandeling van bevestigde post-operatiewe naarheid en braking in pediatriese pasiënte van twee jaar en ouer, kan ONDANSETRON BIOTECH toegedien word deur stadige binneaarse-inspuiting teen 'n dosering van 0,1 mg/ kg tot 'n maksimum van 4 mg.
Herhaalde doserings vir pediatriese pasiënte wat aanhoudende naarheid en/of braking ondervind, is nog nie bestudeer nie, en moet dus nie gegee word nie.
Bejaarde pasiënte:
Effektiwiteit en verdraagsaamheid in pasiënte oor 65 jaar is soortgelyk as wat in jonger volwassenes waargeneem is, wat aandui dat geen doserings aanpassing of roete van toediening benodig word in bejaardes nie.
Voorkoming en behandeling van post-operatiewe naarheid en braking
Volwassenes:
Onmiddellik voor induksie van narkose, of post-operatief indien die pasiënte naarheid en/of braking ondervind na sjirurgie, dien 4 mg onverdund binnespiers of binneaars toe.
Indien binneaars toegedien word, moet dit in nie minder as 30 sekondes toegedien word nie, verkieslik oor 2- 5 minute. Andersins, vir die voorkoming van post-operatiewe naarheid en braking, kan 16 mg mondelings (film-bedekte tablette) gegee word, een uur voor die induksie van narkose.
Herhalende dosering vir pasiënte wat aanhoudend naarheid en/of braking post-operatief ondervind, is nie bestudeer nie. Alhoewel dit aanbeveel word as 'n vasgestelde dosering vir almal, is min pasiënte bo 80 kg of onder 40 kg bestudeer.
Kinders:
Vir die voorkoming van post-operatiewe naarheid en braking in pediatriese pasiënte twee jaar en ouer wat sjirurgie ondergaan onder algemene narkose, kan ONDANSETRON BIOTECH toegedien word deur stadige binneaarse-inspuiting teen 'n dosis van 0,1 mg/kg tot en met 'n maksimum van 4 mg net voor, of na induksie van narkose.
Vir die behandeling van bevestigde post-operatiewe naarheid en braking in pediatriese pasiënte van twee jaar en ouer, kan ONDANSETRON BIOTECH toegedien word deur stadige binneaarse- inspuiting teen 'n dosering van 0,1 mg/ kg tot 'n maksimum van 4 mg.
Herhaalde doserings vir pediatriese pasiënte wat aanhoudende naarheid en/of braking ondervind, is nog nie bestudeer nie, en moet dus nie gegee word nie.
Bejaardes:
Veiligheid en effektiwiteit van ONDANSETRON BIOTECH vir die voorkoming en behandeling van post-operatiewe naarheid en braking in bejaardes, is nog nie vasgestel nie.
Pasiënte met renale/hepatiese inperking:
Pasiënte met renale inperking: Geen aanpassing van daaglikse dosering of frekwensie van dosering, of roete van toediening is noodsaaklik nie. Daar is beperkte inligting beskikbaar oor erge ingekorte nier of lewer inperking.
Pasiënte met hepatiese inperking:
Ontruiming van ONDANSETRON BIOTECH is merkbaar verminder en serum halfleeftyd merkbaar verleng in pasiënte met matige of erge inperking van hepatiese funksie. In hierdie pasiënte, moet 'n daaglikse dosis van 8 mg nie oorskry word nie.
ONDANSETRON BIOTECH inspuiting moet nie saam met ander medikasie in dieselfde inspuiting of infusie toegedien word nie.
ONDANSETRON BIOTECH inspuiting ampules, moet nie gesteriliseer word in 'n outoklaaf nie.
Aanpasbaarheid met ander binneaarse vloeistowwe:
ONDANSETRON BIOTECH inspuiting moet slegs met aanbevole infusie oplossings gemeng word. Binneaarse-oplossings moet voorberei word ten tye van infusie.
ONDANSETRON BIOTECH inspuiting is stabiel vir sewe dae teen kamertemperatuur onder fluoressent beligting of in 'n yskas in die volgende binneaarse infusie vloeistowwe:
5% glukose oplossing; 0.9% natriumkloried oplossing; 10% mannitol oplossing of Ringers oplossing.
Aanpasbaarheid studies is onderneem in poliëtileen sakke en in helder glas flesse.
Merk dat ONDANSETRON BIOTECH inspuiting wat reeds met aanpasbare infusie vloeistowwe gemeng is, in stabiele polipropileen inspuitings geberg moet word.
MERK: Voorbereiding moet onder toepaslike aseptiese omstandighede gedoen word, indien berging vir langer periodes nodig is.
Aanpasbaarheid met ander medisyne
NOTA: Die word nie aanbeveel dat medikasie vir infusie gemeng word nie.
ONDANSETRON BIOTECH inspuiting mag toegedien word deur binneaarse infusie teen 1 mg/ uur bv. deur middel van 'n infusie sak of inspuitings-pomp. Die volgende medikasie mag wel toegedien word via die ONDANSETRON BIOTECH Y-stel, vir ondansetron konsentrasies van 16 tot 160 mikrogram /ml (bv. 8 mg/500 ml en 8 mg/50 ml onderskeidelik.)
Sisplatien: Konsentrasies tot en met 0,48 mg/ml (bv.. 240 mg in 500 ml) toegedien oor een tot agt ure.
Deksmetasoon: Deksmetasoon natrium fosfaat 20 mg mag toegedien word as 'n stadige binneaarse inspuiting oor 2-5 minute via die Y-stel of 'n infusie stel tydens toediening van 8 mg ONDANSETRON BIOTECH verdun in 50-100 ml van 'n aanbevole infusie vloeistof oor ongeveer 15 minute. Aanpasbaarheid tussen deksmetasoon natrium fosfaat en ONDANSETRON BIOTECH is gedemonstreer, wat die gesamentlike toediening van die middels deur dieselfde toedieningstel ondersteun, Dit lei tot in-lyn konsentrasies van 32 µg - 2,5 mg/ml vir deksmetasoon natrium fosfaat en 8 µg -1 mg/ml vir ONDANSETRON BIOTECH.
5-Fluorourasil: Konsentrasies tot 0,8 mg/ml (bv. 2,4 in 3 liter, of 400 mg in 500 ml) toegedien teen 'n koers van ten minste 20 ml per uur (500 ml per 24 uur). Hoër konsentrasies van 5-Fluorousil infusie mag tot 0,045% m/v magnesium kloried bevat tesame met ander afvalstowwe wat aanvaarbaar bewys is.
Karboplatien: Konsentrasies binne die perke van 0,18 mg/ml tot 9,9 mg/ml (bv. 90 mg in 500 ml tot 990 mg in 100 ml), toegedien oor 10 minute tot een uur.
Etoposied: Konsentrasies binne die perke van 0,14 mg/ml tot 0, 25 mg/ml (bv. 72 mg in 500 ml tot 250 mg in 1 liter), toegedien oor 30 minute tot een uur.
Seftazidiem: Doserings binne die perke van 250 mg tot 2000 mg gemeng met Water vir Inspuiting BP, soos aanbeveel deur die vervaardiger (bv. 2,5 ml vir 250 mg en 10 ml vir 2 g seftazidiem), en toegedien as binneaarse bolus inspuiting oor ongeveer 5 minute.
Siklofosfamied: Dosering binne die perke van 100 mg tot 1 g, gemeng met Water vir Inspuiting BP, 5 ml per 100 mg Siklofosfamiede, soos aanbeveel deur die vervaardiger, en toegedien as 'n binneaarse bolus inspuiting oor ongeveer 5 minute.
Doksirubisien: Dosering binne die perke van 10 tot 100 mg, gemeng met Water vir Inspuiting BP, 5 ml per 10 mg doksirubisien, soos aanbeveel deur die vervaardiger, en toegedien as binneaarse bolus inspuiting oor ongeveer 5 minute.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Die volgende newe-effekte kan voorkom:
Sentrale Senuwee Sisteem
Hoofpyn. Konvulsies is al aangemeld, maar is raar.
Kardiovaskulêre Sisteem
Aritmieë, hipotensie, bradikardie en borspyn word selde aangemeld.
Gastrointestinale Sisteem
Verhoging van dikderm transisie tyd is 'n bekende oorsaak van ondansetron en kan lei tot konstipasie in sommige pasiënte.
Hipersensitiwiteits reaksies
Onmiddellike hipersensitiwiteitsreaksies, soms erg (bv. anafilakse, brongospasma, kortasem, hipotensie, skok, angioedeem, urtikaria), is al aangemeld.
Muskuloskeletale
Seldsame onwillekeurige bewegings versteurings sonder definitiewe bewyse van aanhoudende kliniese gevolge .
Lokale reaksies
Pyn, rooiheid en branderigheid by die toedienings-area van die inspuiting.
Ander
'n Warm sensasie of blosing, hik en verbygaande, asimptomatiese verhoging van aminotransferase.
Duiseligheid en verbygaande visuele versteurings (bv. versteurde visie) is al aangemeld kort na vinnige binneaarse toediening van ONDANSETRON BIOTECH.
Spesiale Voorsorgmaatreëls
Hipersensitiwiteitsreaksies is al aangemeld in pasiënte wat hipersensitiwiteit teenoor ander selektiewe 5-HT reseptor antagoniste getoon het.
Pasiënte wat tekens van subakute intestinale obstruksie toon, moet gemonitor word na toediening aangesien ondansetron bekend is om dikderm transisie tyd te verleng.
Omdat die produk aspartaam bevat, word sorg aanbeveel in pasiënte met fenielketonurie.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN BEHANDELING DAARVAN:
Sien NEWE-EFFEKTE en SPESIALE VOORSORGMAATREËLS.
Manifestasies wat aangemeld is, sluit in konstipasie, visuele versteurings, hipotensie, en 'n vasovagale episode met verbygaande tweede graadse AV blok. In gevalle waar oordosering vermoed word, moet toepaslike simptomatiese en ondersteunende terapie gegee word, aangesien daar nie 'n teenmiddel vir ondansetron is nie.

IDENTIFIKASIE:
ONDANSETRON 4 mg/ 2 ml BIOTECH: 'n Helder, kleurlose oplossing, meestal vry van visuele partikels.
ONDANSETRON 8 mg/4 ml BIOTECH: 'n Helder, kleurlose oplossing, meestal vry van visuele partikels.

AANBIEDING:
ONDANSETRON 4 mg/ 2 ml BIOTECH:
2 ml helder glas ampules (5 ampules verpak in 'n karton)
ONDANSETRON 8 mg/4 ml BIOTECH:
4 ml helder glas ampules (5 ampules verpak in 'n karton)

BERGINGSAANWYSINGS:
Bewaar teen of benede 25°C.
Beskerm teen lig.
HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIE NOMMERS:
ONDANSETRON 4 mg/ 2 ml BIOTECH: 38/5.10/0200
ONDANSETRON 8 mg/4 ml BIOTECH: 38/5.10/0217

NAAM EN BESIGHEIDSADRES VAN REGISTRASIE SERTIFIKAAT HOUER:
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