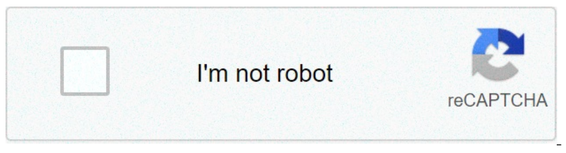

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Directions of use LenexatÃ ¢ â® is indicated to neutralize the sedative effects exerted by benzodiazepines on the central nervous system. It should therefore be used in intensive anesthesia and treatment for the following indications: in anesthesiology closure of induced general anesthesia and maintained with benzodiazepines in hospitalized patients. Neutralization of the sedative effects of benzodiazepanics in short-term diagnostic and therapeutic procedures in hospitalized and outpatient patients. The neutralization of paradoxical reactions of benzodiazepines. In the treatment of diagnosis and intensive treatment of overdose with benzodiazepines. To determine, in the event of an unknown decisive cause, if the drug in question is a benzodiazepine, another drug or is intended for brain injury. To neutralize, in particular, the effects exercised on the central nervous system for excessive doses of benzodiazepines (spontaneous restoration and consciousness to avoid intubating and consequences). Patient precautions with severe cranial trauma (and / or intracranial intracranial pressure) treated with LenexatÃ ¢ â® to reverse the effects of benzodiazepines, can develop an increase in intracranial pressure. The use of LenexatÃ ¢ â® is not recommended in Epilaric patients, who receive benzodiazepanic treatment from a prolonged period. Although LenexatÃ ¢ Â® exercises a slight anticonvulsive intrinsic effect, the sudden suppression of the protective effects of an agonist benzodiazepanic can lead to convulsion frames in epylic patients. Superdosage even when administered at the dose of 100 mg, too excess symptoms were observed. As for the abstinence symptoms attributed to the agonists, see Standard Dosage. Attention: When used in anesthesiology at the end of surgery, LenexatÃ ¢ Â® should not be administered before the disappearance of the peripheral Miorelaxant effect. ATTENTION: This product is a new drug and even if the search conducted to have effectiveness and safety if correctly indicated, unpredictable adverse reactions can still be described or known indicated. In case of suspected adverse reaction, the responsible counter must be notified. Each drug should be kept out of the reach of children. Pharmacological interactions LenexatÃ ¢ â® blocks the central effects of the competitive interaction benzodiazepines at receptor level, the effects of non-benzodiazepanic agonists such as ZopyClone, Triazolopyridazinas and others are also blocked by LenexatÃ ¢ Â® interactions with other states observed depressers snc. The Pharmacokine of benzodiazepine remains unchanged in the presence of LenexatÃ ¢ â®. Particular attention is necessary when using LenexatÃ ¢ â® in cases of overdose from a mixture of drugs, given that tubal effects (such as convulsions and cardiac arrhythmias) of other medicines taken in case of overdose (especially antidepressants CÃƒÂ³licos) can Being displayed with the inversion of the benzodiazepanic effect LenexatÃ ¢ Â®. Breastfeeding even if studies in animals treated with high doses of LenexatÃ ¢ â® revealed evidence of embryotoxicity or teratogenicity, the minor principle of non-administration must be observed in the first months of pregnancy, if not when absolutely necessary. LenexatÃ ¢ Â® administration In emergency situations is not contraindicated during breastfeeding. PRODS LABORATORY. Roche quamms. Farms. S. Contraindices LenexatÃ ¢ â® is contraindicated in patients with recognized hypersensitivity to Flumazenyl. He interferes with the ability to drive vehicles and other ambulatory psychomotor activities. Although after intravenous administration of patients LenexatÃ ¢ â® becoming awake and conscious, They must be advised not to use dangerous machinery or direct vehicles during the first 24 hours after administration, since the effect of benzodiazepanic initially ingested can reappear. In mixed intoxications with benzodiazepanic and cyclic antidepressants, the toxicity of antidepressants can be masked by the protective effects of benzodiazepines. In the presence of autonomous (-Olymal against), neurological or cardiovascular (abnormal motor) or cardiovascular symptoms caused by severe joint intoxication / Tetracular, LenexatÃ ¢ Â® should not be used to reverse the effects of benzodiazepanic. Similarly, users can have convulsion benzodiazepanic after the use of LenexatÃ ¢ â® which can represent a serious action of acute removal week. In case of appearance of these symptoms, injections of small doses of benzodiazepanics restore table. These side effects can be avoided with the slow use of small doses of LenexatÃ ¢ â®, which will be increased with caution according to the patient's need. INJECTABLE SOLUTION Presentation - 5 ml Vial from 0.5 mg - boxes with 5 vials. Adult use and Pediom 8-Fluoro-5.6-Diadom-5-methyl-6-bone-4h-imidazole [1.5a] [1,4] benzodiazepine -3-carboxylate of ethyl. Vial containing 0.5 mg of active substance in 5 ml of aqueous solution (for intravenous administration) with the following excipients: ethylenediaminotheric acid, occupy acid, sober chloride, sodium hydroxide and distilled water. Principle Therapeutic class Active Flumazenil benzodiazepinic antagonists Lenexat with dosage, directions, side effects, interactions and other information. All the information contained in the Lenexat Bula has the intention of informing and educating, in no way to replace the guidelines of a doctor or serve as a recommendation for any type of treatment. Decisions relating to the treatment of patients with Lenexat should be taken by authorized professionals, taking into account the characteristics of each patient. Roche Presentation Lenexat solution for injection. Intravenously. Box with 5 ml 5 vials. Adult use and pediaric composition every vial containment: active ingredient: Flumazenil (8-Fluoro-5.6-Diadom-5-methyl-6-bone-4h-imidazole [1,5A], 4] benzodiazepine Ã ¢ â,¬ " 3-carboxylate of ethyl) Ã ¢ â,¬ | Ã ¢ â,¬ | | " | "| Ã ¢ â,¬ |" | â,¬ | | | O. lenexat Ã ¢ â,¬ "Indications LenexatÃ ¢ â® (Flumazenyl) is indicated in the complete or partial overturning of the central sedative effects of benzodiazepines. Therefore, it is used in anesthesia and intensive care unit in the following indications: in anesthesiology Closure * of induced general anesthesia and maintained with benzodiazepines in hospitalized patients; * the neutralization of the sedative effects of benzodiazepanics in short-term diagnostics and therapeutic procedures in hospitalized and outpatient patients. In intensive care and handling of unconsciousness of unknown origin * diagnostics and treatment of superdose with benzodiazepines; * Determine, in the event of unconscious cause, if the drug in question is a benzodiazepine; * to neutralize, in particular, the effects exercised on the central nervous system for excessive doses of benzodiazepines (spontaneous restoration and consciousness to consciousness to avoid the consequent to Estubaz ion e. Against LetExat Directions LenexatÃ ¢ â® (Flumazenyl) is contraindicated in patients with recognized hypersensitivity Flumazenyl or in patients treated with benzodiazepines to control conditions potentially represent life (eg intracranial pressure control or of the Epilable State). Special maintenance warnings are needed when the use of LenexatÃ ¢ â® (Flumazenyl) is in cases of mixed intoxication, as the Tubic effects (such as convulsions or cardiac arrhythmias) of these drugs associated with overdose (antidepressants in particular cyclical) They can arise with the inversion of the effects of benzodiazepanic. The use of LenexatÃ ¢ â® (Flumazenyl) is not recommended in patients receiving the Epilable Benzodiazepanic treatment from a prolonged period. Although LenexatÃ ¢ Â® (Flumazenyl) exercising a slight anticonvulsive intrinsic effect, abrupt suppression of the protective effects of a Benzodiazepanic agonist can lead to convulsion frames in epilable patients. Patients who receive LenexatÃ ¢ Â® (Flumazenyl) for the reversal of the effects of benzodiazepines must be monitored with regard to the silk recipe, respiratory depression or another residual benzodiazepanic effect, for an adequate period, depending on the dose and the duration of the effects of Benzodiazepanic dependent. When LenexatÃ ¢ â® (Flumazenyl) is used with neuromuscular blockers, it must not be injected until the effects of the latter are completely inverted. Attention: when used in anesthesiology at the end of surgery, LenexatÃ ¢ â® (Flumazenil) should not be administered before the disappearance of the peripheral mordillant effect. LenexatÃ ¢ Â® (Flumazenil) should be used with caution in patients with cranial trauma in use of benzodiazepines, as it can trigger convulsions or alter brainwelling. Rapid injections of LenexatÃ ¢ â® (Flumazenyl) should be avoided in patients exposed to high doses and / or long periods to benzodiazepines, up to a week before the use of LenexatÃ ¢ Â® (Flumazenyl), as it can trigger the Symptoms of abstinence, including agitation, anxiety, emotional labilities, mild confusion and sensory distortions (see dosology point). LenexatÃ ¢ â® (Flumazenil) is not recommended for the treatment of benzodiazepine dependence, nor for the abstinence treatment of benzodiazepanic abstinence. LetExatÃ ¢ Â® (Flumazenil) must be used with caution for the reversal of conscious satin cutters in 1-year-old children for the treatment of superdose in children, for the resuscitation in question © M-NATO and for the inversion of sedative effects Of benzodiazepines used to induce general anesthesia in children. Effects on the ability to drive vehicles and the use of machinery even though after the intravenous administration of LenexatÃ ¢ â® (Flumazenyl) patients become awake and conscious, they should be warned so that they do not direct or manage hazardous machines during the first 24 hours, as the effects of benzodiazepines can reappear. Pharmacological interactions Lenexat LenexatÃ ¢ â® (Flumazenil) blocks the central effects of the benzodiazepines of competitive interaction at the reception level. The effects of non-benzodiazepanic agonists, such as ZopyClone, triazolopyridazins and others, are blocked by LenexatÃ ¢ â® (Flumazenil). Interactions have been observed with other depressers snc. The Pharmacokine of Benzodiazepanic agonists remains unchanged in the presence of LenexatÃ ¢ â® (Flumazenyl) and vice versa. There are no pharmacokinetic interactions between LenexatÃ ¢ â® (Flumazenil) and ethanol, Midazolam or Diazepam. Adverse reactions / Side effects Lenexat LenexatÃ ¢ â® (Flumazenil) is well tolerated in adults and children. In adults, it is well tolerated even when it exceeds the recommended dosage. Anxiety complaints, palpitations and fear after LenessatÃ ¢ â® (Flumazenil) rapid injection were observed. These undesirable effects generally do not require specific treatment. There are convulsive crisis reports in epilable patients or severe hepatic impairment, especially after long treatment with Or in case of mixed intoxication. In cases of mixed intoxication, mainly with cyclical antidepressants, thunder (such as convulsions and cardiac arrhythmias) the inversion of LenexatÃ ¢ ® (Flumazenyl) benzodiazepines can occur. The symptoms of Weekroom abstinence can occur after LenexatÃ ¢ â® (Flumazenil) in patients undergoing long benzodiazepanic treatments in previous weeks. There are panel attachment cases with the use of LenexatÃ ¢ ® (Flumazenil) in patients with a Sendrome rigor history. In some cases, occurrences of nausea has been reported and / or visits during use in anesthesiology. No changes to hepatic or renal function has been observed. LetExat Ã ¢ â,¬ "LenexatÃ ¢ â® (Flumazenil) must be administered exclusively by anesthesiologist or anesthetic expert. LenexatÃ ¢ Â® (Flumazenyl) can be administered by infusion IV diluted in 5% glucose solution, lactate ringer or chloride of sodium at 0.9%, in conjunction with other revenue procedures. If LenexatÃ ¢ â® (Flumazenyl) is sucked for the syringe or mixed with one of the above solutions, it must be discarded in 24 hours. The dose must be titled To get the desired effect. Considering that the duration of the action of some benzodiazepanics can overcome LenexatÃ ¢ â® (Flumazenil), repetitions the dose can be requested if the satin pattern recurs after the patient wake up. In anesthesiology the recommended initial dose Is 0.2 mg administered via iv in 15 seconds. If the desired degree of consciousness is not obtained in 60 seconds, a second dose (0.1 mg) can be administered. Subsequent doses (0.1 mg) can Repeated ssere at 60 second intervals, if necessary, at the total dose of 1 mg. The usual dose is 0.3 Ã ¢ â,¬ "0.6 mg, but the individual needs can vary, depending on the dose and duration of the effects of the administered benzodiazepany and characteristics of the patient. LenexatÃ ¢ Â® Administration (Flumazenyl) In patients treated for several weeks with benzodiazepines should be slow, as the abstinence symptoms may arise. In the event of the appearance of these symptoms, diazepam or midazolam intravenously, slowly, entitled the dose based on the patient's response. In intensive care or unknown cause approach the recommended initial dose is 0.3 mg iv if the desired degree of consciousness is not obtained in 60 seconds, the subsequent doses of LenexatÃ ¢ â® (Flumazenil) can be made to the patient To be awake or the total dose of 2 mg. If you return, LenexatÃ ¢ â® (Flumazenyl) can be administered in the form of intravenous injection in a bole as described above, or in the form of infusion of 0.1 Ã ¢ Â, ¬ "0.4 mg / Now. Infusion speed must be individually adjusted to the desirable level of awakening. If a significant improvement in the state of respiratory function consciousness and does not get after repeated doses of LenexatÃ ¢ â® (Flumazenil), you should think of Benzodiazepan etiology. In intensive treatment unit, it has observed abstinence symptoms when LetExatÃ ¢ â® (Flumazenyl) was slowly administered at patients treated for several weeks with high doses of benzodiazepines. In the event of unexpected symptoms, diazepam or midazolam properties must be carefully based on the patient's response. Children> 1 year of age for reversion conscious benzodiazepanic surveyor induced in children> 1 year of age, the recommended initial dose is 0.01 mg / kg (up to 0, 2 mg) with intravenous administration in 15 seconds. If the desired degree of consciousness is not obtained after 45 seconds, a new dose of 0.01 mg / kg (+ 0.2 mg) can be administered and repeated at intervals of 60 seconds (up to a maximum of 4 times more) or maximum dose of 0.05 mg / kg, or 1 mg, which is smaller. The dose should be individualized according to the patient's response. Super Dosage There is limited experience of acute superdose from LenexatÃ ¢ Â® (flumazenil) in humans. No one else has any specification from antiquity for overdose with LenexatÃ ¢ Â® (flumazenil). The treatment of a superdose with LenexatÃ ¢ ® (Flumazenyl) should consist of general supportive measures, including monitoring of vital signs and observation of the patient's clinical status. Even when administered in higher doses are recommended, they were observed symptoms of overdose. As for the withdrawal symptoms attributed to agonist, see item dosage. Pharmacodynamic Pharmacodynamic characteristics LenexatÃ ¢ ® (Flumazenyl), imidazo-benzodiazepine, is a benzodiazepanic antagonist which specifically blocks, for competitive inhibition, the central effects of substances that act through receptors benzodiazepanic. In experimental studies on animals, the effects of the compounds which exhibit affinity for benzodiazepanic receptors were blocked. In healthy volunteers, LenexatÃ ¢ Â® (flumazenil) administered intravenously antagonized silk, amnesia and psychomotor changes produced by benzodiazepanic agonists. LenexatÃ ¢ Â® (Flumazenyl) did not affect in animal experiments, the effects of substances that do not show affinity for benzodiazepanic receptors, as barbitulic, ethanol, meterbamate, GABA-agonist and mimics of adenosine receptors. However, we lock the effects of non benzodiazepanic benzodiazepanic receptors, as cyclopyrrolones (zopyclone, for example) and triazolopyridazins. The hypnotal, inhibition sedative effects and psychomotive of benzodiazepanic are quickly neutralized after intravenous administration (1-2 minutes) of LenexatÃ ¢ ® (Flumazenil). These effects may reappear in a few hours, depending on the substances used benzodiazepanic half-life and the relationship between the doses of antagonists and agonists administered. LenexatÃ ¢ Â® (flumazenil) is well tolerated even in high doses. toxicological studies in animals have shown that LenexatÃ ¢ ® (Flumazenil) has a low toxicity being devoid of mutagenic activity. LenexatÃ ¢ ® (Flumazenil) may have a weak intrinsic agonist activity, such as the anticonvulsant activity. In animals treated with high doses of benzodiazepines over several weeks, LenexatÃ ¢ Â® (Flumazenyl) resulted in withdrawal symptoms. similar effect was observed in adult humans. Pharmacokines LenexatÃ Pharmacokinetic ¢ Â® (flumazenil) Pharmacokine (flumazenil) is dose-dependent up to 100 mg. Distribution LenexatÃ ¢ ® (Flumazenyl), low lipofilical base, presents speed connection of plasma proteins â â order of 50%. About two tits are bound to albumin. Flumazenil is extensively distributed in the extravascular space. The plasma concentration of Flumazenyl, during the distribution phase, decreases with the half-life of 4 Ã ¢ â ¬ "11 minutes. The volume of distribution at steady state is 0.9 Ã ¢ â ¬" 1.1 l / kg. Flumazenyl metabolism is extensively metabolized in the tender notice. The carboxylic acid is its main metabolic in plasma (free form) and urine (free form and its glucuronide). This metaballite no agonist or antagonist activity in pharmacological tests benzodiazepanic. Elimination LenexatÃ ¢ Â® (flumazenil) is eliminated almost completely (99%) Extra-renal. Practically no one else has any excretion of flumazenil unchanged in the urine, suggesting complete degradation of the drug. The elimination of the drug marked by radioactivity is substantially complete within 72 hours, with 90 Ã ¢ â ¬ "95% of the radioactivity present in the urine and 5 Ã ¢ â ¬" 10% in the faeces. The elimination is faster as evidenced by its low half-life of 40 Ã ¢ ¬ "80 minutes. O. Total plasma Flumazenyl is 0.8 Ã ¢ â,¬ "1.0 l / h / kg and can be assigned almost entirely hepatic clearance. Renal clearance low innex suggests an effective drug resorption after glomerular filtration. Food administration during an infusion intravenous of LenexatÃ ¢ Â® (Flumazenyl) has determined a 50% increase in clearance, mainly due to increased hepatic blood flow that accompanies the meal. Pharmacokine in particular clinical situations in subjects with hepatic impairment, LenexatÃ ¢ Â® half-life arrangement (Flumazenil) is larger and total blood purification is that in healthy individuals. The pharmacokinitis drug is not significantly influenced in the elderly, by sex, in patients in hemodiÃ ¢ nolise, or renal failure. The half-life Elimination in children above 1 year of life is more variable than adults, in 40 minutes and usually varies between 20-75 min. Clearance and distribution volume Ne, regularized body weight, are the adults themselves. Efficiency translates Flumazenil was the first Benzodiazepanic antagonist available for clinical use, reversing all the effects of benzodiazepines without compromising its bioavailability. In the clinical context, the Flumazenyl is used to antagonize the following effects of benzodiazepanics in the following order of the receptor day occupation: anesthesia, hypnosis and muscle relaxation (60-90% occupation), intense silk, amnÃ © ia, reduction of the Attention and light silk (50% occupation), anticonvulsivante and Anxiolatic (20-25% occupation or) 3. Furthermore, Flumazenil reverses the potentially dangerous physiological adverse effects of benzodiazepines, such as respiratory and cardiovascular depression, and obstruction of the various roads. In several clinical studies benzodiazepanic injected and maintained in plasma concentrations of constant infusion and therefore flumazenyl has been administered intravenously and has been shown to quickly restore depressive effects of midazolam, diazepam, lorazepam or flunitrazepam1,2,3, 4 In a double-decked placebo-controlled study, duration of various doses of Flumazenyl (0.2 mg, 0.6 mg, 1.0 mg and 3.0 mg) in volunteers, 3.0 mg of flumazenyl products reversing satin pattern with Midazolam (0.17 mg / kg / h) longer than other Tested3 doses. In another double blind and open studio in 110 patients with unconscious suspected superdose benzodiazepanic 2-4 in matteo and the coma lawson scale, the flumazenyl was used to evaluate its efficiency, utility and safety. The first 31 patients are Double-blind states with Flumazenyl (1mg dosing atom) or saline solution, while the remaining patients were dealt with openly flumazenyl to recovering consciousness or to reach the maximum injected dose of 2.5 mg. Double-blind phase patients, 14 of the 17 patients aroused after the mother of 0.8 Ã ± 0.3 (EP) MG compared to 1 on 14 patients treated with placebo (p. In a review of 30 studies on the superdose intentionally administered by Patients, involving 760 patients, in which the flumazenyl was used as an antagonist benzodiazepanic, the following results were observed:. 10 of the studies were double-blind and the remaining 20 the variation of the flumazenyl dose used in these studies was 0 , 3 to â,¬ "10mg. In double blind studies, 94% of patients who received Flumazenil has resumed knowledge in less than 15 minutes, while waking occurred only in 10% of patients treated with placebo. When all studies were grouped, 84% of patients, who had not suffered mixed intoxication, awakened with Flumazenil. In these studies, the Tracheal Entrupation was needed in 78 And the extubation was possible in 20 of them. The Entubao was avoided in another 14 patients who have awakened when the Flumazenil was Administered1. So, due to its effectiveness, the introduction of flumazenil is an important, since it has increased the induced benzodiazepanic sedation sedation sedation, so that one of its most common uses is the closure of induced general anesthesia and maintained with benzodiazepine and therapeutic therapeutic therapeutic therapy and thirsty, along with use in the treatment of superdose benzodizanic and in the setosity of serious patients maintained in intensive care unit. Bibliographic references 1. Park gr, Navapurkar V, Ferenci P. The role of Flumazenil in the critical conditions. Acta Anaesshosiol Scand. 1995; 39 (Suppl 108): 23-34. 2. 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