1-Actions and clinical pharmacology
Domifor (propodit) is an intervenous hyporic agent for use in the induction and maintenance of general amenithesia or session.
The day, an ship-free informated in an oil-waste emulsion, is chemically desired from currently available intervenous areathetic agents. Intervenous injection of a flerequeuic dose of propodit produces hyporosis regoldy and smoothly, usually within 40 socools
Pharmacokhoritics in adults

The Pharmacokhoritics in adults in the Pharmacokhoritics in the Pharmacokho

Pharmacolivation in adults
The pharmacolivation ground of proposition can be described by a 3-compartment open model. After a single bolus dose, there is stall dissipation by the pharmacolivation ground of proposition can be asserted by a 3-compartment open model. After a single bolus dose, there is stall dissipation from blood into issues (type: 1.1 to 1.8 min, high metabolic desarrace (type) 3-to 0 of min) and sterming to the proposition of the state of

store elimination from poorly perfuend tissues (I<sub>1,07</sub>: 114-440 mil). With 12 are 24 hour samplings, I<sub>1,07</sub> values of 502 and 40ff. The respectively were observed.

After the respective were observed and the respective were observed.

After the respective were the respective were observed and the respective were observed.

After the respective were the respective were observed and the respective were observed and the respective were observed and the respective were the respectiv

serbidical compartment (IVc) is between 21 and 58 L (0.3.6.3.0.5 May based on a folk patient), and the victime of distribution of strong terminal content of the serbidical co

used. Obeyly is associated with significantly larger volumes of destitution (1991 L versus 153.1) and desarance rates (2.8 Limin versus 1.8 Limin but there is no charge in the demination hallow. When given by an infacion for up to two houses, the pharmacointexts of propoful appear to be independent of dose (10.5 - 10.5 reg)-pharmacointexts. Primarocolates are linear over recommended of the register of the proposition of the pharmacointext of proposition of the pharmacointext of the pharmacointext of proposition variations the Dosepa and administration; industrial control and pharmacointext of proposition variations the Dosepa and administration; industrial control and proposition variations the Dosepa and administration; y and stability, Pre-mixing with alfentanil). inetics in adult patients in Intensive Care Unit (ICU)

Pharmacokinetics in adult patients in intensive Care Unit (ICU)

Regarding nod parameters, the pharmacokinetic of proposal of in these patients are similar to those of patients underground proposal parameters. The pharmacokinetic in children is the patients of the patients are similar to those of patients underground patients. The results were obtained in AGA 1 shadow, many parameters. The results were obtained in AGA 1 shadow, many ping in age from 3 to 10 years, who necived a simple blust dose of proposal.

The results were obtained in AGA 1 shadow, many ping in age from 3 to 10 years, who necived a simple blust dose of proposal distributions. The results were obtained in AGA 1 shadow, many ping in age from 3 to 10 years, who necived a simple blust dose of proposal distributions. The results are obtained to the parameters of t

preferable over intermittent bolus administration in order to minimize underside cardioreganizery effects. If the elseky, dibilitation AACA BLI or IV preferable, napid (engle or respect bolus does does deministration should not be used for elsevirable in should not be used to reductive (see Wirmorgs), and ACA BLI or IV preferable english of the elsevirable english elsevirable

## 2- Indications and clinical use

Domitter is das included for predictive meditación in châme 3 years of age and older. Comections sedificien for a simple and dissipanticle procedures. Adultri: Domitter, when administered ix as directed, can be used lo initiate and maintain sediation localizaçõesia amentician in placifica unifergio supricipal procedures (see Walmings and Precaudiors). Domitter may also be used for sediation during diagnostic procedures (see Walmings and Precaudiors), procedure, as seleja and efficacy have no been established.

The restrictions that apoly to intervenous for emulations whold also be considered when using Dermiller in the ICU.

The restrictions that apoly to intervenous descriptions are supported to a proper to the construction of the ICU.

Externior can should be used in administrativing Dermiller in adjoint, descriptions are should be used in administrativing Dermiller in adjoint, descriptions are should be used in administrativing Dermiller in adjoint, descriptions are should be used in administrativing Dermiller in adjoint, descriptions are should be used in administrativing Dermiller in adjoint, descriptions are should be used in administrativing Dermiller in adjoint, descriptions are should be used in administrativing Dermiller in adjoint and adjoint and administrative descriptions. The verifical is capabile of supporting rapid growth of microproprise (see Prescultors and Dosagn and administrative). Fast when the developed supplies described and administrative and Dosagn and administrative. The verifical is capabile of supporting rapid growth of microproprise (see Prescultors and Dosagn and administrative). The verifical is capabile of supporting rapid growth of microproprise (see Prescultors and Dosagn and administrative). The verifical is capabile of supporting rapid growth of microproprise (see Prescultors and Dosagn and administrative). The verifical is capabile of supporting and administrative and the prescultor and administrative and administrative

The results were obtained in ASA indutions, ranging in age from 3 to 10 years, who necessed a step to botal dose of propodity and a state of the company of

Material Process of a Microst Control appeals and process of a Microst Control appeal and process of a Microst Control appeal and process of a Microst Control appeal and process of a Microstan Control appeals and a Microstan Control appeal and a Microstan Control appeals and a Microstan Control appeals and a Microstan Co

Demilier (proposit) is a short-acting ix general anesthesia porting in the commendation and maintenance of anesthesia porting ix general anesthesia general anesthesi

Use in the elderly Elderly patients may be more sensitive to the effects of Dormifor, therefore, the dosage of Dormifor should be reduced in these patients according to their condition and clinical response (see Pharmacokinetics and Dosage and administration). Cardiac anesthesis

Cardiac anesthesia Propolici I, emission was evaluated in 328 patients undergrain; coronary artery bypass graft (CABG). Of these patients 85% were makes (nean age 61, range 32-83) and 15% were fearmate; (mean age 62, range 42-86). The mappin's plate that sometignance (CABG and post ell eventroise fractions. Department is no platefast with poor left ventriouslar fram equity of platefast with poor left ventriouslar fram expert of platefast with poor left ventriouslar framework of platefast ventriouslar framework of pla who are remandary interaction of Dormifor. In those patients where additional fluid therapy may be contrainficated, other measures, e.g., elevation of lower externities, or use of pressor agents, may be useful to offset the hypotension which is associated with the induction of anesthesia with Dormifor.

Neurosurgical anesthesia When using Domition in patients with increased intracrarial pressure (ICP) or impaired cerebral circulation, significant decreases in mean arterial pressure should be avoided because of the resultant decreases in cerebral perfusion pressure. When increased ICP is suspected, byperentiation and hypocrable should accompany the administration of Domiffer (See Dosage and administration)

Drug interactions

Proposed it, emulsion has been used in association with spinal and epidural anesthesia and with a range of premedicants
muscle relaxants, inhabitional agents, analgesic agents and with local anesthetic agents; no significant adverse interaction
have been observed.

6- Adverse reactions

6 - Adverse reactions

Ansethesia and section for surgical/diagnostic procedures

During induction of insettless in niceal times, hypotens on an object of patients operand process. The invisions of During induction of insettless in niceal times, hypotens on an object of patients opportung times. The invisions of the invision of the scale of the invision of the inv

ness, which may be accompanied by an increase in muscle tone. This may or many not be preceded by a print of of waterfulness. There have been reported protected protection of the protection of

season following the use of proposal is a emulsion for industria

and to intensive care sectation. Acquisal relationship has not been clearly established. The following balls compares the overall occurrence rates of adverse reactions in propofol i.v. emulsion patients from non-ICU and ICU clinical trists where the rate of occurrence was greater than 1 %. Major differences include tack of metabolic hutdriffered (hyperdipensis) and respiratory events in the non-ICU group and lack of nausea, vomiting, headache, movement and injection site events in the ICU group.

movement and injection site events in the ICU group. Non-ICU vs. ICU adverse events occurring in greater than 1% of propofol i.v. emulsion patients.

Number of patients		2588	127
Cardiovascular	Hypotension	7.38 %	31.50 %
	Bradycardia	2.82 %	3.94 %
	Hypertension	2.82 %	1.57 %
	Amhythmia	1.24 %	0.79 %
	Tachycardia	0.81 %	3.15 %
	Cardiovascular Disorder	0.23 %	2.36 %
	Hemorrhage	0.23 %	1.57 %
	Atrial Fibrillation	0.15%	1.57 %
	Cardiac Arrest	0.12 %	3.15 %
	Ventricular Tachycardia	0.08 %	1.57 %
Digestive	Nausea	14 57 %	0.%
	Vomiting	8.31 %	0.%
	Abdominal Cramping	1.24 %	0 %
Nervous	Movement	4.44 %	0.%
	Headache	1.78 %	0 %
	Dizziness	1.70 %	0 %
	Twitching	1.47 %	0 %
	Agitation	0.19 %	2.36 %
	Intracranial Hypertension	0 %	3.94 %
Metabolic/Nutritional	Hyperlipemia	0.08 %	5.51 %
	Acidosis	0.04 %	1.57 %
	Creatinine Increased	0 %	2.36 %
	BUN Increased	0 %	1.57 %
	Hyperglycemia	0 %	1.57 %
	Hypernaturemia	0 %	1.57 %
	Hypokalemia	0%	1.57 %
Respiratory	Dyspnea	0.43 %	1.57 %
	Hypoxia	0.08 %	6.30 %
	Acidosis	0%	1.57 %
	Pneumothorax	0%	1.57 %
Other	Injection Site:		
	Pain	8.11 %	0 %
	Burning/stinging	7.77 %	0 %
	Fever	1.89 %	2.36 %
	Hiccough	1.78 %	0 %
	Cough	1.55 %	0 %
	Rash	1.20 %	1.57 %
	Anemia	0.35 %	1.57 %

Kidney Fallure 0 % 1
Adverse reactions reported at an incidence of 1.0 % or less during anesthesia and sedation for surg ular System: Significant hypotension, premature atrial contractions, premature ventricular contraction

procedures:
Cardiovascular System: Significant hypotension, premature atrial contractions, premature ventricular co ladiycardia, syncope, abnormal ECG, bigeminy, edema.
Respiratory System: Burning in Broat, lachypnea, dyspnea, upper airway obstruction, wheezing, bron larypropasam, proventilation, speechrafilation, anexeing.

Ecitatory, Hyperdonia, dystonia, rigids, tremor.

Central Nervous System: Confusion, dizziness, paresthesia, somnolence, shivering, abnormal dreams, agitation, deliriur.

euphoria, fatigue. Injection Site: Phlebitis, thrombosis, hives/fitching, redness/discolouration. Digestive System: Hypersalivration, dry mouth. Sitin and Appendages: Flushingstein flor incidence in children, see above), urticaria, pruritus. Special Senses: Diplopia, amblyopia, tinnitus.

Special Sensex: Diplops, amblyops, firmitus
Muscucloskelses: Mysaja.
Urogenita: Urine retention, discolouration of urine.
Adverse reactions reported at an incidence of 1% or less during ICU sedation.
Cardiovascular: Arrhythmia, extrasystole, heart block, right heart failure, bigemin
myocardal infection.

myocardal infaction.

Respiratory: Lung function decreased, respiratory arrest.

Central Nerocus System. Seizure, thinking abnormal, akathisia, chills, anxiety, confusion, hallucinations.

Deserver Res. Pepplamegaly.

Propobal I, v. emultion therapy was initiated at an influsion rate of 5.5 mg/kg/hr and thrated as needed to maintain sedation at a standardized level. The results of the study showed an increase in the number of earth in patients treated with propoble in the propobal I, v. emultion 2% settlement group, and (45%) in the proposal I, v. emultion 2% settlement group, and (45%) in the SSA treatment group.

SSA treatment group.

SSA treatment group.

The study of the study o

Drug abuse and dependence: Rare cases of self administration of propofol i.v. emulsion by health care professionals have been reported, including some fatalities.

onen ingornen, incursing journel unasisses.

7- Symptoms and treatment of overdosage.

To date, there is no brown case of acute overdosage, and no specific information on emergency treatment of overdosage cases.

To date, there is no brown case of acute overdosage, and no specific information should be discontinued immediately acute of the control o

flow ratio of intraversors fluids and of severe may require the administration of plasma vicume expanders and/or pressor agents.

8- Dosage and administration
Sircl septic techniques must always be maintained during handing as Domitter (propods) is a single-sep personnel.

Sircl septic techniques must always be maintained during handing as Domitter (propods) is a single-sep personnel.

For a personnel of the septic sep

Most adult palems under 55 years of aga and classified ASA I and I are likely to require 2.0 to 2.5 mg/g of Dormfer for adultion when unpermissibled or when premisdented with an elevandapargene or inflamazion transcribe. For induction, against the response of the patient until the clinical signs show the creat of general amenthesia. It is exportant to be familiar and experienced with the appropriate informations used in the complete for the strating elselvy, against the response of the patient until the clinical signs show the creat of general amenthesia. It is exportant to be familiar and experienced with the appropriate information used to the strategies of the patient of the strategies of the strategies of the strategies of the patient of the strategies of t

During cardiac amenthesis, a raight bobus induction should be avoided. A slow rate of approximately 20 mg every 10 seconds under induction rates (10 5 1.5 mg/sight should be used Most children one of years of age require approximately 22 mg/sight and the property of the control of the property of the control of the property of the control of the con

\*\*Montherance of general anesthesia 
Maintenance of general anesthesia 
Anesthesia can be maintained by administering Dorniflor by influsion or intermittent I.v. bolus injection. The patient's clinical 
Anesthesia can be maintained by administering Dorniflor by influsion or intermittent injections.

When administering Dorniflor by influsion, drop counters, syringe pumps or volumetric pumps must be used to provide 
Administering Dorniflor by influsion, drop counters, syringe pumps or volumetric pumps must be used to provide 
Administering Dorniflor by influsion, drop counters, syringe pumps or volumetric pumps must be used to provide 
Administering Dorniflor by influsion, drop counters, syringe pumps or volumetric pumps must be used to provide 
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Permitting with afferthatill position or planning of the parket is clinical suppose and independent in the fluid project. An expending of incremental implications. The parket is clinical suppose and independent the fluid project of the amount and response project of incremental implications. The parket is clinical suppose and incremental implications. The project of incremental implications of incremental implications. The project of incremental implications of incremental implications. The project of incremental implications of

Domiflor is administered for sedation, rates of administration should be individualized and Brated to clinical prost patients, the rates of Domiflor administration will be approximately 25 to 30% of those used for learnance of general ansistemas.

gi militation of sedation, slow injection or slow infusion techniques are preferable over rapid bolus administration. During tenance of sedation, variable rate infusion is preferable over intermittent bolus dose administration. During tenance of sedation, variable rate infusion is preferable over intermittent bolus dose administration.

maintainment of radiation, a variable that influence of the control of production of the control of the control

responses to stimulation are obtained in order to arrow assumer summer or contained in order to arrow assumer summer or contained in order to arrow assumer summer or contained in order to arrow assumer or contained in order to arrow assumer or contained in order to arrow assumer or contained in the design of the contained in the design of the contained in order to arrow assumer or contained in the design of the contained in the design of the contained in the position of the contained in the con

Rapid (injective or regardisci) blooks do do designations should not be used for sealation in these patients (see Winnings). Dominally should be individualized according to the patients condition and response, blook glip optiols, and vital signa. Adults: For instantic, mechanismly weetlated, adult patients, literative Care Unit (ICU) sedation should be instituded along the contraction should be serial and some contraction should be serial and some contraction should be included and the contraction of t

susceptible to hypotension.

Children under 18 years of age: Proposal is contraindicated for the sectation of children 18 years or younger receiving

DOSAGE AND ADMINISTRATION

DOBAGE AND ADJanus Industrial MUCLINION CONTROL AND STATE OF SHOULD ADJANUS IN MACHINE IN A MUCLINION CONTROL AND STATE OF SHOULD AND STATE OF SHO

mg every 10 seconds until induction ones() but does should be carefully titted to effect.

Cardiac anesthesis: Patients are likely to require 0.5 to 1.5 mg/kg (approximately 20 mg every 10 seconds until induction ones() but does should be carefully titted to effect.

Cardiac anesthesis: Patients are likely to require 0.5 to 1.5 mg/kg (approximately 20 mg every 10 seconds until induction ones(). reduction onset).

deurosurgical Patients: Are likely to require 1.0 to 2.0 mg/kg (approximately 20 mg every 10 seconds until solution onset).

induction onset).

Seedative Patientis: Children over 8 years of age require approximately 2.5 mg/kg.

Thidren 3 to 8 years of age may require somewhat higher doses but doses should be titrated slowly to the
selseved effect. In the absence of sufficient clinical expenseror, to portfair is not recommended for anesthesia in
rhildren less than 3 years of age (see Indications and clinical use and Precautions).

Reduced dosage is excommended for children of ASA Classes Ill and IV.

Reduced dosage is recommended for children of ASA Classes III and IV.

INNICE OF GENELA ANESTHESIA:

Variable rate infusion distated to the desired clinical effect
Adult Patients Less than 55 Years of Age: Generally, 0.10 to 0.20 mg/kg/min (6 to 12 mg/kg/h).

Elberly, Debilitated ander Adult ASA III or IV Patients Cenerally, 0.05 to 0.10 mg/kg/min (3 to 6 mg/kg/h).

Elderij, Debilitated ander Adult ASA III er ir Patentins: Genemany, 1.0.0 to 1.0.0 mg/mg/m-Jardica naethesian Most pateints regundo, 20,000 d. 0,10 to 0,15 mg/kg/min (6 to 9 mg/kg/h). Primary Dormiflor with Secondary Opioid - 0,30 to 0,15 mg/kg/min (6 to 8 mg/kg/h). Lou Duce Dormiflor with Primary Opioid - 0,30 to 0,10 mg/kg/min (6 to 8 mg/kg/h). Paediatric Patients: Generally, 0,10 to 0,25 mg/kg/min (6-15 mg/kg/h).

Intermitted Predictive Plateints: Generally, 0.1 to 0.25 mg/sg/min (el-15 mg/sg/m).

BURGICALDIGANOSTIC SERDATION

Disage and rate should be individualized and trivated in the desired difficient effect

Disage and rate should be individualized and trivated in the desired difficient effect

Disage and rate should be individualized and trivated in the desired difficient effect

Disage and rate should be individualized and trivated in the desired difficient effects

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Elderly, debellised, flypowedness in continued to the desired desired and the desired desir

mnutes. Subsequent increments of 0.005 to 0.010 mg/kg/min (0.3 - 0.6 mg/kg/m) yeer 5 to 10 minutes may be used until desired level of seddation is achieved. For maintenance, not speaker the service of the control of the service of

Paediatric Patients: See Contraindications
Compatibility and stability

possumity and statistics of the state of the

Common put no security of the common security of the common security of the common put no security of the common security of the com

métanol, isocotane.

11.1 in water, 19°C.

Common proposition de la marte mediation. Each mit contains 10 mg of proposition for i v. administration. In addition the active composition, proposition, the remaistion abso contains soybean oil (100 mg/mll, glycerol (22.5 mg/ml) photophaside (12 mg/ml) and water for injection with sodium hydroxide to adjust pit. It is isotonic with a pit of 7.5-8.5.

Dilution for iz. Infusion

INF - IT ESENTIATIONS
Dormiflor 1% is available in different packs containing:
5 glass vials with 20 ml emulsion.
5 glass ampoules with 20 ml emulsion.
1 glass sival with 50 ml emulsion.

r. Jorden Pharma S.p.A. Caponago, Italy ARIWAN Pharmaceutical Industries Lebanon s.a.l. Jadra, Lebanon

THIS IS A MEDICAMENT

ects your health, and its consumption contrary on, the method of use and the instructions of the experts in medicines, their benefits and risks.

Council of Arab Health Ministers, Union of Arab Pharmacists