Package leaflet: Information for the patient

ESMOCARD 100 mg/10 ml solution for injection
Esmolol hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What ESMOCARD 100 mg/10 ml solution for injection is and what it is used for
2. What you need to know before you use ESMOCARD 100 mg/10 ml solution for injection
3. How to use ESMOCARD 100 mg/10 ml solution for injection
4. Possible side effects
5. How to store ESMOCARD 100 mg/10 ml solution for injection
6. Contents of the pack and other information

1. What ESMOCARD 100 mg/10 ml solution for injection is and what it is used for

ESMOCARD 100 mg/10 ml belongs to the group of beta blockers. These medicines slow down the heartbeat and reduce blood pressure.

ESMOCARD 100 mg/10 ml is used for short-term treatment if your heart beats too fast.

ESMOCARD 100 mg/10 ml is also used during or straight after surgery if your blood pressure gets too high and/or your heart beats too fast.

2. What you need to know before you use ESMOCARD 100 mg/10 ml solution for injection

Your doctor will not give you ESMOCARD 100 mg/10 ml if:
- You are allergic to esmolol hydrochloride. The signs of an allergic reaction include shortness of breath, wheezing, rash, itching or swelling of your face and lips
- You have a very slow heart beat (less than 50 beats per minute)
- You have a fast or alternating fast and slow heartbeat
- You have something called “severe heart block”. Heart block is a problem with the electrical messages that control your heartbeat
- You have low blood pressure
- You have a problem with the blood supply to your heart
- You have serious heart failure symptoms
- You are receiving or have recently received verapamil. You must not be given ESMOCARD 100 mg/10 ml within 48 hours of when you stop receiving verapamil
- You have a gland disease called phaeochromocytoma which has not been treated. Phaeochromocytoma arises from the adrenal gland and may cause a sudden increase in blood pressure, severe headache, sweating and increased heartbeat
- You have increased blood pressure in the lung (pulmonary hypertension)
- You have asthma symptoms that are worsening rapidly
- You have increased level of acids in your body (a problem called metabolic acidosis)

You will not be given ESMOCARD 100 mg/10 ml if any of the above applies to you. If you are not

sure if you have any of these conditions, talk to your doctor or nurse before having ESMOCARD 100 mg/10 ml.

Warning and Precautions

Talk to your doctor or nurse before being given ESMOCARD 100 mg/10 ml. Your doctor will take special care with this medicine if:

- You are being treated for certain heart rhythm disorders called supraventricular arrhythmias and you:
    - Have other heart problems or
    - Are taking other heart medicines

  Use of ESMOCARD 100 mg/10 ml in this way can lead to severe reactions which may be fatal including:
    - Loss of consciousness
    - Shock (when your heart does not pump enough blood)
    - Heart attack (cardiac arrest)
- You develop low blood pressure (hypotension). The signs of this may be feeling dizzy or light headed, especially when standing up. This is rapidly reversible with dosage reduction or discontinuation. Usually, your blood pressure and ECG will be continously monitored if you are treated with ESMOCARD 100 mg/10 ml. Low blood pressure usually gets better within 30 minutes of the end of your ESMOCARD 100 mg/10 ml treatment.
- You have a low heart rate before treatment
- Your heart rate decreases to less than 50 to 55 beats per minute. If this happens your doctor may give you a lower dose or stop treatment with ESMOCARD 100 mg/10 ml
- You have heart failure
- You have problems with the electrical messages that control your heartbeat (heart block)
- You have a gland disease called phaeochromocytoma which has been treated with medicines called alpha-receptor blockers
- You are being treated for high blood pressure (hypertension) which has been caused by low body temperature (hypothermia)
- You have narrowing of your airways or wheezing, such as with asthma
- You have diabetes or low blood sugar (hypoglycaemia). You require special monitoring because esmolol can mask the symptoms of a low blood sugar. ESMOCARD 100 mg/10 ml can increase the effects of your diabetes medicines.
- You develop skin problems. These can be caused by the solution leaking around the site of the injection. If this happens your doctor will use a different vein for your injection
- You have a particular type of angina (chest pain) called 'Prinzmetal's angina'
- You have low blood volume (with low blood pressure). You could develop circulatory collapse more easily
- You have circulatory problems, such as paleness of your fingers (Raynaud's disease) or aching, tired and sometimes burning pains in your legs.
- You have kidney problems. If you have kidney disease or you need kidney dialysis you could develop high blood potassium levels (hyperkalemia). This can cause serious heart problems.
- You have any allergies or are at risk of anaphylactic reactions (severe allergic reactions). ESMOCARD 100 mg/10 ml can make allergies more severe and more difficult to treat
- You or any of your family have a history of psoriasis (where your skin produces scaly patches)
- You have a disease called hyperthyroidism (an overactive thyroid gland).

Changing the dose is not usually necessary if you have liver problems.

If any of the above apply to you (or you are not sure), talk to your doctor or nurse before being given this medicine. You may need to be checked carefully and your treatment may be changed.

Other medicines and ESMOCARD 100 mg/10 ml solution for injection
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, herbal medicines, or natural products.

Your doctor will check that any medicines you are taking will not alter the way that ESMOCARD 100 mg/10 ml works.

In particular, tell your doctor or nurse if you are taking any of the following:
- Medicines that can lower the blood pressure or slow the heart rate
- Medicines used to treat heart rhythm problems or chest pain (angina) such as verapamil and diltiazem. You should not receive ESMOCARD 100 mg/10 ml within 48 hours of stopping verapamil
- Nifedipine, which is used to treat chest pain (angina), high blood pressure and Raynaud's disease
- Medicines used to treat both heart rhythm problems (such as quinidine, disopyramide, amiodarone) and heart failure (such as digoxin, digitoxin, digitalis)
- Medicines used to treat diabetes, including insulin and medicines taken by mouth
- Medicines known as ganglion blocking agents (such as trimetaphan)
- Medicines used as pain killers, such as non-steroidal anti-inflammatory drugs known as NSAIDs
- Floctafenine, which is a pain killer
- Amisulpride, a medicine that is used to treat mental problems
- 'Tricyclic' antidepressant medicines (such as imipramine and amitriptyline) or any other drugs for mental health problems
- Barbiturates (such as phenobarbital, used to treat epilepsy) or phenothiazines (such as chlorpromazine, used to treat mental disorders)
- Clozapine which is used to treat mental disorders
- Epinephrine, which is used to treat allergic reactions
- Medicines used to treat asthma
- Medicines used to treat colds or a blocked nose, called nasal 'decongestants'
- Reserpine, which is used to treat high blood pressure
- Clonidine, which is used to treat high blood pressure and migraine
- Moxonidine, which is used to treat high blood pressure
- Ergot derivates, medicines mainly used to treat Parkinson's disease
- Warfarin, which is used to thin your blood
- Morphine, which is a strong pain killer
- Suxamethonium chloride (also known as succinylcholine or scoline) or mivacurium, which is used to relax your muscles, usually during an operation. Your doctor will also take special care when using ESMOCARD 100 mg/10 ml during operations, when you will be having anaesthetics and other treatments.

If you are not sure if any of the above applies to you, talk to your doctor or nurse before having ESMOCARD 100 mg/10 ml.

Tests you may have while ESMOCARD 100 mg/10 ml is used
The use of medicines such as ESMOCARD 100 mg/10 ml over a long period of time can cause a reduction in the force of your heartbeat.
Since ESMOCARD 100 mg/10 ml is only used for a limited time, this is unlikely to happen to you.
During treatment you will be carefully monitored and ESMOCARD 100 mg/10 ml treatment will be reduced or stopped if the force of your heartbeat is reduced.
Your doctor will also check your blood pressure while you are being treated with ESMOCARD 100 mg/10 ml.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
Insufficient data are available about the use of esmolol during pregnancy in humans to prove safety. However, there are no indicators of increased risk of birth defects in humans. Because of the lack of experience the use of ESMOCARD 100 mg/10 ml during pregnancy is not recommended.

Tell your doctor if you are breast-feeding. ESMOCARD 100 mg/10 ml may pass into breast milk, so you should not be given ESMOCARD 100 mg/10 ml if you are breast-feeding.

Ask your doctor for advice before taking any medicine.

ESMOCARD 100 mg/10 ml solution for injection contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. How to use ESMOCARD 100 mg/10 ml solution for injection

The dosage must be individually adapted. A starting dosage followed by a maintenance dosage should be administered. Your doctor will determine the dosage scheme and adapt the dosage as needed based on the side effects.

ESMOCARD 100 mg/10 ml is administered as an injection. It is administered into a vein by a doctor or a nurse.

The duration of use depends on the effect and possibly occurring side effects. Your doctor will determine the duration of treatment.

Changing the dose of ESMOCARD 100mg/10 ml is not usually necessary if you:
- have liver problems

If you have kidney problems then your doctor will take appropriate caution.

The Elderly
Your doctor will start your treatment with a lower dose.

Use in children and adolescents
The safety and efficacy of ESMOCARD 100 mg/10 ml have not been established in children and adolescents. Children up to the age of 18 years should not receive ESMOCARD 100 mg/10 ml.

If you have received more ESMOCARD 100 mg/10 solution for injection than you should
As you are being given ESMOCARD 100 mg/10 ml by a trained and qualified person, it is unlikely that you will have too much. However, if this happens the doctor will stop ESMOCARD 100 mg/10 ml and give you additional treatment, if necessary.

If you think that a dose of ESMOCARD 100 mg/10 ml solution for injection has been forgotten
As you are being given ESMOCARD 100 mg/10 ml by a trained and qualified person, it is unlikely that you will miss a dose. However, if you think that you have missed a dose, talk to your doctor or nurse as soon as possible.

When the use of ESMOCARD 100 mg/10 ml solution for injection is stopped
Suddenly stopping ESMOCARD 100 mg/10 ml may cause symptoms of rapid heartbeat (tachycardia) and high blood pressure (hypertension) to return. To avoid this your doctor should stop your treatment gradually. If you are known to have coronary artery disease (this may be associated with a history of angina or heart attack) your doctor will take special care when stopping treatment with ESMOCARD 100 mg/10 ml.

If you have any further questions on the use of this product, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Most side effects disappear within 30 minutes of stopping treatment with ESMOCARD 100 mg/10 ml.
The following side effects have been reported with ESMOCARD 100 mg/10 ml:

Tell your doctor or nurse straight away if you notice any of the following side effects, which can be serious. The infusion may also need to be stopped.

Very common (may affect more than 1 in 10 people):
- Fall in blood pressure. This can be rapidly corrected by reducing the dose of ESMOCARD 100 mg/10 ml or stopping the treatment. Your blood pressure will be measured often during treatment.
- Excessive sweating

Common (may affect up to 1 in 10 people):
- Loss of appetite
- Feeling anxious or depressed
- Dizziness
- Feeling sleepy
- Headache
- Tingling or "pins and needles"
- Difficulty concentrating
- Feeling confused or agitated
- Feeling or being sick (nausea and vomiting)
- Feeling weak
- Feeling tired (fatigue)
- Irritation and hardening of your skin where ESMOCARD 100mg/10ml was injected

Uncommon (may affect up to 1 in 100 people):
- Abnormal thoughts
- Sudden loss of consciousness
- Feeling faint of fainting
- Fits (seizures or convulsions)
- Problems with speech
- Problems with eyesight
- Slow heart rate
- Problems with the electrical messages that control your heartbeat
- Increased pressure in the arteries of the lungs
- Inability of the heart to pump enough blood (heart failure)
- A disruption in the rhythm of the heart sometimes known as palpitations (ventricular extrasystoles)
- A heartbeat disorder (nodal rhythm)
- Chest discomfort caused by poor blood flow through the blood vessels of the heart muscle (angina pectoris)
- Poor circulation in your arms or legs
- Looking pale or flushed
- Fluids on your lungs
- Shortness of breath or tightness of the chest making it difficult to breathe
- Wheezing
- Blocked nose
- Abnormal rattling/crackling sounds when breathing
- Changes in your sense of taste
- Indigestion
- Constipation
- Dry mouth
- Pain in your stomach area
- Discoloured skin
- Reddening of the skin
- Pain in your muscles or tendons, including around the shoulder blades and ribs
- Problems passing urine (urinary retention)
- Chest pain
- Feeling cold or high temperature (fever)

- Pain and swelling (oedema) of your vein where ESMOCARD 100 mg/10 ml was injected
- Burning feeling at the site of injection

Very rare (may affect up to 1 in 10,000 people):
- Severe reduction in heart rate (sinus arrest)
- No electrical activity in the heart (asystole)
- Tender blood vessels with an area of hot red skin (thrombophlebitis)
- Dead skin caused by the solution leaking around the site of injection

Not known (the number of people affected is unknown):
- Increased levels of potassium in the blood (hyperkalemia)
- Increased levels of acids in your body (metabolic acidosis)
- Increased rate of contraction of the heart (accelerated idioventricular rhythm)
- Spasm of the artery in the heart
- Failure of the normal circulation of the blood (cardiac arrest)
- Psoriasis (where your skin produces scaly patches)
- Swelling of the skin of the face, limbs, tongue or throat (angioedema)
- Hives (urticaria)
- Inflammation of a vein or blistering at the site of infusion.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ESMOCARD 100 mg/10 ml solution for injection

Do not store above 25°C. Keep the vial in the outer carton in order to protect from light

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label of the vial after EXP. The expiry date refers to the last day of that month.

The opened product is stable for 24 hours at 2°C-8 °C. However, it should be used immediately after opening. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C unless opening has taken place in controlled and validated aseptic conditions.

Do not use ESMOCARD 100 mg/10 ml if you notice particles or discolouration of the solution.

Do not throw away any medicines via wastewater or household waste. Ask your doctor how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What ESMOCARD 100 mg/10 ml.**contains**
- The active substance is esmolol hydrochloride.
- Each vial of 10 ml solution for injection contains 100 mg esmolol hydrochloride. 1 ml aqueous solution contains 10 mg esmolol hydrochloride.
- The other ingredients are sodium acetate trihydrate, acetic acid 99%, hydrochloric acid (for pH adjustment), water for injections.

What ESMOCARD 100 mg/10 ml **looks like and contents of the pack**
ESMOCARD 100 mg/10 ml solution for injection is clear and colourless, available in glass vials containing 10 ml solution each.
The vial is of colourless glass (type I) and has a chlorobutyl rubber stopper.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Orpha-Devel Handels und Vertriebs GmbH
Wintergasse 85/1B
A-3002 Purkersdorf
Austria

Manufacturer
G.L. Pharma GmbH
Arnethgasse 3
1160 Vienna
Austria

AOP Orphan Pharmaceuticals GmbH
Leopold-Ungar-Platz 2
1190 Vienna
Austria

This medicinal product is authorised in the Member States of the EEA under the following names:

Czech Republic:	ESMOCARD 10mg/ml injekčni roztok
Denmark:	ESMOCARD injektionsvæske, opløsning 10 mg/ml
Finland:	ESMOCARD 10 mg/ml injektioneste, liuos
France:	ESMOCARD 100 mg/10 ml, solution injectable
Germany:	ESMOCARD 100 mg/10 ml Injektionslösung
Greece:	ESMOCARD 100 mg/10 ml ενέσιμο διάλυμα
Hungary:	ESMOCARD 10 mg/ml oldatos injekció
Ireland:	ESMOCARD 100 mg/10 ml solution for injection
Italy:	ESMOCARD 100 mg/ 10 ml soluzione iniettabile
Netherlands:	Esmolol HCl Orpha 100 mg/10 ml oplossing voor injective
Poland:	Esmocard 100 mg/10 ml, roztwór do wstrzykiwań
Slovakia:	Esmocard 100mg/10ml injekčný roztok
Slovenia:	Esmocard 10 mg/ml raztopina za injiciranje
Sweden:	Esmocard 10 mg/ml injektionsvätska, lösning
United Kingdom:	Esmolol hydrochloride 10 mg/ml solution for injection

This leaflet was last revised in 09/2021

The following information is intended for healthcare professionals only:

This section contains practical information regarding administration. Read the SPC for full information on posology and method of administration, contraindications, warnings etc.

Esmocard 100 mg/10 ml solution for injection in a vial with 10 ml is a clear solution ready for intravenous use. The concentration of this product is 10 mg/ml esmolol hydrochloride.

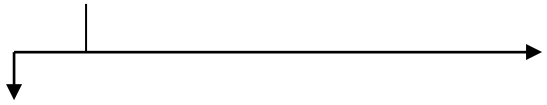
SUPRAVENTRICULAR TACHYARRHYTHMIA

The dosage of Esmocard 100 mg/10 ml should be titrated individually. A starting dose is required, followed by a maintenance dosage.

The effective dose of Esmocard 100 mg/10 ml is within the range of 50 to 200 micrograms/kg/min, although doses as high as 300 micrograms /kg/min have been used. In a few patients the average effective dosage of 25 micrograms /kg/min has been adequate.

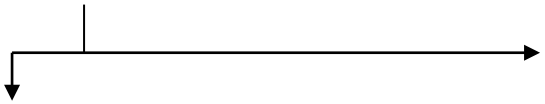
Flow Chart for Initiation and Maintenance of Treatment

Loading dosage infusion of
500 micrograms/kg/min for 1 minute,
THEN 50 micrograms/kg/min for 4 minutes



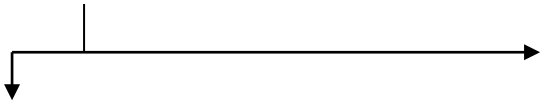
Response
Maintain infusion at
50 micrograms/kg/min

Inadequate response within 5 minutes
Repeat 500 micrograms/kg/min for 1 minute
Increase maintenance infusion to 100 micrograms/kg/min for 4 minutes



Response
Maintain infusion at
100 micrograms/kg/min

Inadequate response within 5 minutes
Repeat 500 micrograms/kg/min for 1 minute
Increase maintenance infusion to 150 micrograms/kg/min for 4 minutes



Response
Maintain infusion at
150 micrograms/kg/min

Inadequate response
Repeat 500 micrograms/kg/min for 1 minute
Increase maintenance infusion to 200 micrograms/kg/min and maintain

As the desired heart rate or safety endpoint (e.g. lowered blood pressure) is approached, OMIT the loading infusion and reduce the incremental dose in the maintenance infusion from 50 micrograms/kg/min to 25 micrograms/kg/min or lower. If necessary, the interval between the titration steps may be increased from 5 to 10 minutes.

NB: Maintenance doses above 200 micrograms/kg/min have not been shown to have significantly increased benefits, and the safety of doses above 300 micrograms/kg/min has not been studied.

In the event of an adverse reaction, the dosage of Esmocard 100 mg/10 ml may be reduced or discontinued. Pharmacological adverse reactions should resolve within 30 minutes.

If a local infusion site reaction develops, an alternative infusion site should be used and caution should be taken to prevent extravasation.

The administration of Esmocard 100 mg/10 ml infusions for longer than 24 hours has not been thoroughly evaluated. Infusion durations greater than 24 hours should only be used with caution.

Conversion table: **microg/kg/min → ml/min** (esmolol diluted to 10 mg/ml strength)							
	500 µg/kg/min	50 µg/kg/min	100 µg/kg/min	150 µg/kg/min	200 µg/kg/min	250 µg/kg/min	300 µg/kg/min
	1 minute only						
kg	**ml/min**	**ml/min**	**ml/min**	**ml/min**	**ml/min**	**ml/min**	**ml/min**
40	2	0,2	0,4	0,6	0,8	1	1,2
45	2,25	0,225	0,45	0,675	0,9	1,125	1,35
50	2,5	0,25	0,5	0,75	1	1,25	1,5
55	2,75	0,275	0,55	0,825	1,1	1,375	1,65
60	3	0,3	0,6	0,9	1,2	1,5	1,8
65	3,25	0,325	0,65	0,975	1,3	1,625	1,95
70	3,5	0,35	0,7	1,05	1,4	1,75	2,1
75	3,75	0,375	0,75	1,125	1,5	1,875	2,25
80	4	0,4	0,8	1,2	1,6	2	2,4
85	4,25	0,425	0,85	1,275	1,7	2,125	2,55
90	4,5	0,45	0,9	1,35	1,8	2,25	2,7
95	4,75	0,475	0,95	1,425	1,9	2,375	2,85
100	5	0,5	1	1,5	2	2,5	3
105	5,25	0,525	1,05	1,575	2,1	2,625	3,15
110	5,5	0,55	1,1	1,65	2,2	2,75	3,3
115	5,75	0,575	1,15	1,725	2,3	2,875	3,45
120	6	0,6	1,2	1,8	2,4	3	3,6

Conversion table: **microg/kg/min → ml/h** (esmolol diluted to 10 mg/ml strength)							
	500 µg/kg/min	50 µg/kg/min	100 µg/kg/min	150 µg/kg/min	200 µg/kg/min	250 µg/kg/min	300 µg/kg/min
	1 minute only						
kg	**ml/h**	**ml/h**	**ml/h**	**ml/h**	**ml/h**	**ml/h**	**ml/h**
40	120	12	24	36	48	60	72
45	135	13,5	27	40,5	54	67,5	81
50	150	15	30	45	60	75	90
55	165	16,5	33	49,5	66	82,5	99
60	180	18	36	54	72	90	108
65	195	19,5	39	58,5	78	97,5	117
70	210	21	42	63	84	105	126
75	225	22,5	45	67,5	90	112,5	135
80	240	24	48	72	96	120	144
85	255	25,5	51	76,5	102	127,5	153
90	270	27	54	81	108	135	162
95	285	28,5	57	85,5	114	142,5	171
100	300	30	60	90	120	150	180
105	315	31,5	63	94,5	126	157,5	189
110	330	33	66	99	132	165	198
115	345	34,5	69	103,5	138	172,5	207
120	360	36	72	108	144	180	216

Abrupt discontinuation of Esmocard 100 mg/10 ml in patients has not been reported to produce the withdrawal effects which may occur with abrupt withdrawal of beta -blockers following chronic use in coronary artery disease (CAD) patients. However, caution should still be used in discontinuing Esmocard 100 mg/10 ml infusions abruptly in CAD patients.

PERIOPERATIVE TACHYCARDIA AND HYPERTENSION

For perioperative tachycardia and hypertension the dosing regimen may vary as follows:

a) For the intraoperative treatment – during anaesthesia when immediate control is required, a bolus injection of 80 mg is given over 15 to 30 seconds, followed by a 150 micrograms/kg/min infusion. Titrate the infusion rate as required up to 300 micrograms/kg/ min.

b) Upon awakening from anaesthesia administer an infusion of 500 micrograms/kg/min for up to 4 minutes followed by an infusion of 300 micrograms/kg/min.

c) For postoperative situations when time for titration is available, give the 500 micrograms/kg/min loading dose over one minute before each titration step to produce a rapid onset of action. Use titration steps of 50, 100, 150, 200, 250 and 300 micrograms/kg/min given over four minutes, stopping at the desired therapeutic effect.

Replacement of Esmocard 100 mg/10 ml therapy by alternative drugs
After patients achieve an adequate control of the heart rate and a stable clinical status, transition to alternative drugs (such as antiarrhytmics or calcium antagonists) may be accomplished.

Reducing the dosage:
When Esmocard 100 mg/10 ml is to be replaced by alternative drugs, the physician should carefully consider the labelling of the alternative drug selected and reduce the dosage of Esmocard 100 mg/10 ml as follows:

1) Within the first hour after the first dose of the alternative drug, reduce the Esmocard 100 mg/10 ml infusion rate by one-half (50%).

2) After administration of the second dose of the other alternative drug, monitor the patient's response and if satisfactory control is maintained for the first hour, discontinue the Esmocard 100 mg/10 ml infusion.

Additional dosing information: as the desired therapeutic effect or a safety endpoint (e.g. lowered blood pressure) is approached, omit the loading dose and reduce the incremental infusion to 12.5 – 25 micrograms/kg/min. Also, if desired, increase the interval between titration steps from five to ten minutes.

Esmocard 100 mg/10 ml should be discontinued when heart rate or blood pressure rapidly approach or exceed a safety limit, and then restarted without a loading infusion at a lower dose after the heart rate or blood pressure has returned to an acceptable level.

Special populations

Elderly
The elderly should be treated with caution, starting with a lower dosage. Special studies in the elderly have not been conducted. However, analysis of data of 252 patients over 65 years indicated that no variations in pharmacodynamic effects occurred as compared with data from patients under 65.
Patients with kidney insufficiency
In patients with renal insufficiency caution is needed when Esmocard 100 mg/10 ml is administered by infusion, since the acid metabolite of Esmocard 100 mg/10 ml is excreted through the kidneys. Excretion of the acid metabolite is significantly decreased in patients with renal disease, with the elimination half-life increased to about tenfold that of normals, and plasma levels considerably elevated.

Patients with liver insufficiency

In case of liver insufficiency no special precautions are necessary since the esterases in the red blood cells have a main role in the Esmocard 100 mg/10 ml metabolism.

Paediatric population (age under 18 years)

The safety and efficacy of Esmocard 100 mg/10 ml in children aged up to 18 years have not yet been established. Therefore, Esmocard 100 mg/10 ml is not indicated for use in the paediatric population.