SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINE

Carbosen con adrenalina 10 mg / ml + 5 micrograms / ml injectable solution.
Carbosen con adrenalina 20 mg / ml + 5 micrograms / ml injectable solution.
Carbosen con adrenalina 20 mg / ml + 10 micrograms / ml injectable solution.

2. QUALITATIVE-QUANTITATIVE COMPOSITION (mg / ml)

The composition is the following:

Composition of vials and cartridges

Active principles	**Carbosen con adrenalina 10 mg/ml + 5 mcg/ml injectable solution**	***Carbosen con adrenalina*** **20 mg/ml + 5 mcg/ml injectable solution**	**Carbosen con adrenalina 20 mg/ml + 10 mcg/ml solution for injection**
Mepivacaine hydrochloride *(equal to Mepivacaine)*	10 mg *(8.7 mg)*	20 mg *(17.4 mg)*	20 mg *(17.4 mg)*
Adrenaline acid tartrate *(equal to Adrenaline)*	0.009 mg *(mg 0.005)*	0.009 mg *(mg 0.005)*	0.018 mg *(0.010 mg)*
Excipients			
Sodium chloride	7.5 mg	6.5 mg	6.5 mg
Sodium metabisulfite	0.5 mg	mg 1	mg 1
Ppiqb water in ml 1			

Composition of bottles

Active principles	**Carbosen con adrenalina 10 mg/ml + 5 mcg/ml injectable solution**	**Carbosen con adrenalina 20 mg/ml + 5 mcg/ml injectable solution**	**Carbosen con adrenalina 20 mg/ml + 10 mcg/ml solution for injection**
Mepivacaine hydrochloride *(equal to Mepivacaine)*	10 mg	20 mg	20 mg
Adrenaline acid tartrate *(equal to Adrenaline)*	0.009 mg *(mg 0.005)*	0.009 mg *(mg 0.005)*	0.018 mg *(0.010 mg)*
Excipients			
Sodium chloride	7.5 mg	6.5 mg	6.5 mg
Sodium metabisulfite	0.5 mg	mg 1	mg 1
Methyl para-hydroxy benzoate	mg 1	mg 1	mg 1
Ppiqb water in ml 1			

3. PHARMACEUTICAL FORM

Injectable solution for local anaesthesia.

4. CLINICAL INFORMATION

4.1 Therapeutic Indications

CARBOSEN CON ADRENALINA is indicated in all interventions of: general medicine (causalgia, neuralgia, etc.), sports medicine (muscle strains, meniscopathies, etc.) orthopaedics (fracture reductions, etc.)

ENT (tonsillectomy, rhinoplasty, interventions on the middle ear, etc.), ophthalmology (retrobulbar block, etc.), dermatology (wart removal, cysts, dermoids, etc.), obstetrics and gynaecology, general surgery (minor surgery), in which prolonged anaesthesia is desired, or obtaining absolute ischemia of the anaesthetized region. The tubular vial form is for the exclusive use of dentists and is indicated in all conservative and surgical interventions in odontostomatology.

4.2 Dosage and method of use
The maximum dose in adults (not treated with sedatives) is of 7 mg / kg, both in single administration and in repeated administrations at an interval of no less than 90 minutes.
Do not exceed a 550 mg dose.
The total dose of 1000 mg should not be exceeded within 24 hours.
Do not exceed the dose of 5-6 mg / kg in paediatrics.
Recommended doses:
In dentistry and stomatology:
For seepage and peripheral nerve block: 30-90 mg.
In surgery:
For peridural and caudal block; para-vertebral block; cervical peripheral nerve block, brachial, intercostal, para-cervical, pudendal and nerve endings: up to 400 mg
In other indications: according to medical prescription.
In obstetrics:
For para-cervical block: up to 200 mg over a 90 minute period.
Warning: the 1-2-5-10-20 ml ampoules and the 1.8 ml cartridges do not contain para-septic excipients, and should be used for a single administration. Any remaining product should be discarded.

4.3 Contraindications
Hypersensitivity already noted towards components or other substances closely correlated from the chemical point of view. Not to be used in the event of verified or presumed pregnancy.
CARBOSEN CON ADRENALINA contains sodium metabisulfite; this substance may cause allergic reactions and severe asthma attacks in sensitive individuals, especially in asthmatics. Adrenaline is contraindicated in principle in cardiopathic patients, in severe arteriopathies, in hypertensive patients, in subjects with ischemic manifestations of any type or with essential migraines, in nephropaths, in those with hyperthyroidism, in diabetics.

4.4 Special warnings and precautions for use
CARBOSEN CON ADRENALINA is used with absolute caution in therapy subjects receiving MAOIs or tricyclic antidepressants.
Before use, verify the patient's circulatory conditions. Avoid overdose and allow at least 24 hours to elapse between two maximum doses.
The solution should be injected with caution, in small doses, 10 seconds after prior aspiration. The patient should be monitored by discontinuing administration immediately if needs be.
In rare cases, serious reactions may occur, even in the absence of individual hypersensitivity, therefore the availability of equipment, drugs and personnel suitable for emergency treatment is necessary.

4.5 Interactions with other drugs
There are no noted interactions with other drugs.
However, caution should be exercised in subjects receiving MAOIs or tricyclic antidepressants.

4.6 Use in pregnancy
Not to be used in the event of verified or presumed pregnancy.

4.7 Effects on driving and use of machines
At the recommended doses, no adverse effects on driving ability or use of machines were reported.

4.8 Undesirable effects

The patient may show toxic and allergic reactions such as the phenomena of: central stimulation with excitement, tremors, disorientation, vertigo, mydriasis, increased metabolism and body temperature, and for very high doses, convulsions.
If the medulla oblongata is involved, there is a sharing of the cardiovascular, respiratory and emetic centres with sweating, arrhythmias, hypertension, tachypnea, bronchodilation, nausea, vomiting.
Peripheral effects may affect the cardiovascular system with bradycardia and vasodilation.
Locally it can cause skin rashes such as hives and itching; there may also be general manifestations such as bronchospasm, laryngeal oedema, up to cardiovascular collapse from anaphylactic shock.
The vasoconstrictor, due to its action on circulation, can cause undesirable effects of various types, especially in non-normal subjects from a respiratory point of view: anxiety, sweating, cardiac arrhythmias, hypertension, acute headache, substernal and pharyngeal pain, photophobia, vomiting.
The patient must be expressly asked to report any undesirable effects not previously described to the doctor.

Reporting of side effects
If any side effects appear, including any possible side effects not listed in this leaflet, talk to your doctor or pharmacist. Side effects can also be reported directly via the national reporting system at http://www.aifa.gov.it/content/segnalazioni-reazioni-avverse. Reporting side effects contributes to providing greater information on the safety of this medicine.

4.9 Overdose

Administration must be stopped at the first warning symptom: it is advisable to place the patient in a horizontal position and ensure airway patency by administering oxygen in the case of severe dyspnoea or performing artificial ventilation. The use of bulbar analeptics should be avoided so as not to aggravate the situation by increasing oxygen consumption.
Any convulsions can be controlled with the use of Diazepam (10-20 mg intravenously), barbiturates that can accentuate bulbar depression are not recommended.
The circulation can be strengthened by administering cortisone drugs in appropriate doses by the intravenous route; dilute solutions of alpha-beta stimulants with vasoconstrictive action or atropine sulphate can be added.
Sodium bicarbonate in an appropriate concentration can be used intravenously as an antacid.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics

Mepivacaine hydrochloride is a long-acting amide-type local anaesthetic.
These pharmacological characteristics have been demonstrated in various experimental animals with different methods.
The analgesic effect was demonstrated by intramuscular administration in mice and by application to the surface of the rabbit cornea.

5.2 Pharmacokinetics

The blood peak of CARBOSEN CON ADRENALINA depends on the type of block and on the concentration of the solution. Employed in various types of block, it reaches the blood peak on average within 60-180 minutes from administration, which is about 2-3 times slower with regard to the product without vasoconstrictor. Furthermore, the presence of adrenaline halves the plasma concentrations of the anaesthetic.
The drug is distributed in the organism's fluids and tissues and its half-life is approximately two hours.

Metabolized in the liver, it is mainly excreted via the renal route, both as such and as a metabolite.

5.3 Preclinical safety data

The LD_{50} of CARBOSEN CON ADRENALINA by iv is 40 mg / kg in the mouse.
For SC administration the LD_{50} of CARBOSEN CON ADRENALINA in mice is 160 mg / kg.
S.c. administration of 10 mg / kg for one month in mice was well tolerated and did not cause any local reactions.
No pathological modifications in body weight, urine, blood pressure and parenchyma were observed in monkeys treated with 10 mg / kg and in rats treated with 3 mg / kg sc for a period of 21 days.
At the application site (superficial, intradermal and subcutaneous) Mepivacaine at therapeutic doses does not cause local irritation phenomena.
No maternal and fetal harm was observed in experimental animals.

6. PHARMACEUTICAL INFORMATION

6.1 Excipients

Carbosen con adrenalina 10 mg / ml + 5 micrograms / ml injectable solution
Carbosen con adrenalina 20 mg / ml + 5 micrograms / ml injectable solution
1-2-5-10-20 ml ampoules: Sodium chloride; Sodium metabisulfite, p.p.i. water
50 ml container: Sodium chloride; Sodium metabisulfite; Methyl parahydroxy benzoate; p.p.i. water

Carbosen con adrenalina 20mg / ml + 10 micrograms / ml injectable solution
1-2-5-10-20 ml ampoules, 1.8 ml cartridge: Sodium chloride; Sodium metabisulfite, p.p.i. water
50 ml container: Sodium chloride; Sodium metabisulfite; Methyl parahydroxy benzoate; p.p.i. water

6.2 Incompatibilities

Not noted

6.3 Validity

36 months. The indicated expiry date refers to the product correctly stored in intact packaging.

6.4 Special precautions for storage

Store away from light, at a temperature not exceeding 25 ° C. Store in the original container.

6.5 Container characteristics and capacity.

Carbosen con adrenalina 10 mg / ml + 5micrograms / ml injectable solution
Carbosen con adrenalina 20 mg / ml + 5 micrograms / ml injectable solution

- Type I glass ampoules of 1-2-5-10-20 ml, for injectable preparations, in packs of 5, 10, 50, 100 ampoules.
- Multidose type II glass bottles with elastomer stopper and aluminium cap, 50 ml, for injectable solutions, in packs of 50 containers.

Carbosen con adrenalina 20 mg / ml + 10micrograms / ml injectable solution

- Type I glass ampoules of 1-2-5-10-20 ml, for injectable preparations, in packs of 5, 10, 50, 100 ampoules.
- Type I glass ampoules with plunger and elastomer under-cap and aluminium cap, 1.8 ml, for injectable preparations, in packs of 5, 50, 100 cartridges.
- Multidose type II glass containers with elastomer stopper and aluminium cap, 50 ml, for injectable preparations, in packs of 5 containers.

6.6 Instructions for Use

None in particular.

7. MARKETING LICENCE HOLDER

Industria Farmaceutica Galenica Senese S.r.l.

8. MARKETING LICENCE NUMBER(S)

Carbosen con adrenalina 10 mg / ml + 5 micrograms / ml injectable solution					
1 ml vial	5 vials	MA No. 030904015	10 ml vial	5 vials	MA No. 030904104
	50 vials	MA No. 030904027		10 vials	MA No. 030904585
	100 vials	MA No. 030904039		50 vials	MA No. 030904116
2 ml vial	5 vials	MA No. 030904041		100 vials	MA No. 030904128
	50 vials	MA No. 030904054	20 ml vial	5 vials	MA No. 030904130
	100 vials	MA No. 030904066		50 vials	MA No. 030904142
5 ml vial	5 vials	MA No. 030904078		100 vials	MA No. 030904155
	10 vials	MA No. 030904573	container		
	50 vials	MA No. 030904080	of 50 ml	5 containers	MA No. 030904167
	100 vials	MA No. 030904092			

Carbosen con adrenalina 20 mg / ml + 5 micrograms / ml injectable solution					
1 ml vial	5 vials	MA No. 030904179	10 ml vial	5 vials	AIC n030904268
	50 vials	MA No. 030904181		10 vials	MA No. 030904609
	100 vials	MA No. 030904193		50 vials	AIC n030904270
2 ml vial	5 vials	MA No. 030904205		100 vials	MA No. 030904282
	50 vials	MA No. 030904217	20 ml vial	5 vials	MA No. 030904294
	100 vials	MA No. 030904229		50 vials	MA No. 030904306
5 ml vial	5 vials	MA No. 030904231		100 vials	MA No. 030904318
	10 vials	MA No. 030904597	container		
	50 vials	MA No. 030904243	of 50 ml	5 containers	MA No. 030904534
	100 vials	MA No. 030904256			

Carbosen con adrenalina 20 mg / ml + 10 micrograms / ml injectable solution					
1 ml vial	5 vials	MA No. 030904546	20 ml vial	5 vials	MA No. 030904407
	50 vials	MA No. 030904419		50 vials	MA No. 030904458
	100 vials	MA No. 030904559		100 vials	MA No. 030904484
2 ml vial	5 vials	MA No. 030904371	cartridge		
	50 vials	MA No. 030904421	1.8 ml	5 cartridges	MA No. 030904496
	100 vials	MA No. 030904460		50 cartridges	MA No. 030904508
5 ml vial	5 vials	MA No. 030904383		100 cartridges	MA No. 030904510
	10 vials	MA No. 030904369	container		
	50 vials	MA No. 030904433	of 50 ml	5 containers	MA No. 030904522
	100 vials	MA No. 030904472			
10 ml vial	5 vials	MA No. 030904395			
	10 vials	MA No. 030904611			
	50 vials	MA No. 030904445			
	100 vials	MA No. 030904561			

9. DATE OF FIRST AUTHORISATION

March 1998

10 DATE OF (PARTIAL) TEXT REVISION

Determined by AIFA on 12 July 2018