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SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicine:

Carbosen 10 mg/ml injectable solution
Carbosen 20 mg/ml injectable solution
Carbosen 30 mg/ml injectable solution

2. Quantitative-quantitative composition (mg/ml):

The composition of CARBOSEN is as follows:

COMPOSITION OF VIALS (1-2-5-10-20 ml) - CARTRIDGES (1.8 ml) - PRE-FILLED SYRINGES (2-5-10)			
Active principles	**10mg/ml**	**20mg/ml**	**30mg/ml**
Mepivacaine hydrochloride *(equal to Mepivacaine)*	10 mg *(8.7 mg)*	20 mg *(17.4 mg)*	30 mg *(26.1 mg)*
Excipients			
Sodium chloride	8 mg	7 mg	6 mg
Water for injection as required to 1ml			
COMPOSITION OF BOTTLES (50 ml)			
Active principles	**10mg/ml**	**20mg/ml**	**30mg/ml**
Mepivacaine hydrochloride *(equal to Mepivacaine)*	10 mg *(8.7 mg)*	20 mg *(17.4 mg)*	30 mg *(26.1 mg)*
Excipients			
Sodium chloride	8 mg	7 mg	6 mg
Methyl para-hydroxy benzoate	1 mg	1 mg	1 mg
Water for injection as required to 1ml			

3. Pharmaceutical form:

Injectable solution for local anaesthesia.

4. Clinical information

4.1 Therapeutic indications:

CARBOSEN 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, and general surgery (minor surgery). 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 preservative 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.

4.4 Special warnings and precautions for use:

CARBOSEN 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 Interaction with other drugs and other forms of interaction

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, tachypnoea, 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 patient must be expressly asked to report any undesirable effects not previously described to the doctor.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important, as it allows for the continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are requested to report any suspected adverse reactions via the national reporting system at http://www.aifa.gov.it/content/segnalazioni-reazioni-avverse.

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 depends on the type of block and on the concentration of the solution. Used in various types of block, it reaches the blood peak on average within 30 minutes from administration.
The drug is distributed in the organism's fluids and tissues and its half-life is approximately two hours. Metabolised in the liver, it is mainly excreted via the renal route, both as such and as a metabolite.

5.3 Pre-clinical safety data

The LD50 for intravenous administration in mice is 40 mg/kg. The LD50 for subcutaneous injection in mice, rabbits and guinea pigs is 260, 110 and 94 mg/kg respectively.
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 s.c. 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 foetal harm was observed in experimental animals.

6. Pharmaceutical information

6.1 Excipients

CARBOSEN 10 mg/ml, 20 mg/ml and 30 mg/ml
1-2-5-10-20 ml vials; 1.8 ml cartridges; 2, 5 and 10 ml single-use pre-filled syringes: Sodium chloride; Water for injectable preparations.
50 ml container: Sodium chloride; Methyl parahydroxybenzoate; Water for injectable preparations.

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 at a temperature not exceeding 25°C in the original packaging. Do not freeze.

6.5 Nature and capacity of the container

CARBOSEN 10 mg/ml and 20 mg/ml
- Type I glass ampoules of 1-2-5-10-20 ml, for injectable preparations, in packs of 5, 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.
- Multi-dose type II glass containers with elastomer stopper and aluminium cap, 50 ml, for injectable preparations, in packs of 5 containers.
- Single-use 5 and 10 ml pre-filled syringes, in sterile blister packs, in individual sachets

CARBOSEN 30 mg/ml
- 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.
- Multi-dose type II glass containers with elastomer stopper and aluminium cap, 50 ml, for injectable preparations, in packs of 5 containers.
- Single-use 2 ml pre-filled syringes, in sterile blister packs, in individual sachets

6.6 Instructions for use

None in particular.

7. Marketing Authorisation Holder

Industria Farmaceutica Galenica Senese srl

8. Marketing authorisation number(s)

CARBOSEN 10 MG/ML					
1 ml vial	5 vials	MA No. 033640501	cartridge	5 cartridges	MA No. 033640386
	50 vials	MA No. 033640083	1.8 ml	50 cartridges	MA No. 033640412
	100 vials	MA No. 033640234		100 cartridges	MA No. 033640448
2 ml vial	5 vials	MA No. 033640513	container		
	50 vials	MA No. 033640119	of 50 ml	5 containers	MA No. 033640475
	100 vials	MA No. 033640261			
5 ml vial	5 vials	MA No. 033640525	pre-filled syringe	1 pre-filled syringe	
	10 vials	MA No. 033640638	of 5 ml	MA No. 033640588	
	50 vials	MA No. 033640145			
	100 vials	MA No. 033640297	pre-filled syringe	1 pre-filled syringe	
10 ml vial	5 vials	MA No. 033640032	of 10 ml	MA No. 033640590	
	10 vials	MA No. 033640640			
	50 vials	MA No. 033640172			
	100 vials	MA No. 033640323			
20 ml vial	5 vials	MA No. 033640057			
	50 vials	MA No. 033640208			
	100 vials	MA No. 033640350			
CARBOSEN 20 MG/ML					
1 ml vial	5 vials	MA No. 033640537	cartridge		
	50 vials	MA No. 033640095	1.8 ml	5 cartridges	MA No. 033640398
	100 vials	MA No. 033640246		50 cartridges	MA No. 033640424
2 ml vial	5 vials	MA No. 033640549		100 cartridges	MA No. 033640451
	50 vials	MA No. 033640121	container		
	100 vials	MA No. 033640273	of 50 ml	5 containers	MA No. 033640487
5 ml vial	5 vials	MA No. 033640018			
	10 vials	MA No. 033640653	pre-filled syringe	1 pre-filled syringe	
	50 vials	MA No. 033640158	of 5 ml	MA No. 033640602	
	100 vials	MA No. 033640309			
10 ml vial	5 vials	MA No. 033640020	pre-filled syringe	1 pre-filled syringe	
	10 vials	MA No. 033640665	of 10 ml	MA No. 033640614	
	50 vials	MA No. 033640184			
	100 vials	MA No. 033640335			
20 ml vial	5 vials	MA No. 033640069			
	50 vials	MA No. 033640210			
	100 vials	MA No. 033640362			
CARBOSEN 30 MG/ML					
1 ml vial	5 vials	MA No. 033640552	20 ml vial	5 vials	MA No. 033640071
	50 vials	MA No. 033640107		50 vials	MA No. 033640222
	100 vials	MA No. 033640259		100 vials	MA No. 033640374
2 ml vial	5 vials	MA No. 033640564	cartridge		
	50 vials	MA No. 033640133	1.8 ml	5 cartridges	MA No. 033640400
	100 vials	MA No. 033640285		50 cartridges	MA No. 033640436

5 ml vial	5 vials	MA No. 033640576		100 cartridges	MA No. 033640463
	50 vials	MA No. 033640160	container		
	100 vials	MA No. 033640311	of 50 ml	5 containers	MA No. 033640499
10 ml vial	5 vials	MA No. 033640044			
	10 vials	MA No. 033640677	pre-filled syringe	1 pre-filled syringe	
	50 vials	MA No. 033640196	of 2 ml	MA No. 033640626	
	100 vials	MA No. 033640347			

9. Date of first authorisation

Carbosen 10 mg/ml, 20 mg/ml and 30 mg/ml vial, cartridge and container: March 1998
Carbosen 10 mg/ml, 20 mg/ml and 30 mg/ml pre-filled syringe: June 2001

10. Date of partial revision of the text: 14 May 2018