GUNA-DIUR- amiloride - apis mellifera - berberis vulgaris fruit - hieracium pilosella flowering top - hydrochlorothiazide - solidago virgaurea flowering top - spironolactone - sus scrofa pituitary gland - solution/ drops
Guna spa

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

GUNA®-DIUR

1. INDICATIONS AND USAGE

1.1 Temporary relief of fluid retention
1.2 Tissue swelling and related disconforts

2. DOSAGE AND ADMINISTRATION

Adults: 20 drops in a little water, 2 times per day for an avarage of two months.

Stop use and ask a doctor if symptoms persist more than 5 days.

Administration may very according to individual needs.

GUNA-DIUR may be used together with other homeopthic medicines.

3. DOSAGE FORMS AND STRENGTHS

3.1. 30 ml Bottle dropper container contains:
Active ingredients: Amiloride 4X 0.006 ml, Apis Mellifica 2X 0.626 ml, Berberis Vulgaris T 0.314 ml, Hydrochlorothiazide 4X 0.006 ml, Hypophysis 12X 6.314 ml, Mouse-Ear Hawkweed T 6.314 ml, Solidago Virgaurea T 0.314 ml, Spironolactone 4X 0.006 ml.
Inactive Ingredient: Ethylic Alcohol 30%

4. CONTRAINDICATIONS

4.1. There is no history of hypersensitivity to GUNA-DIUR. However, do not use if you are hypersensitive to any of the active ingredients of Guna-Diur.

5. WARNINGS AND PRECAUTIONS

5.1. GUNA-DIUR is contraindicated in patients with anuria and in patients with a history of hypersensitivity to Spironolactone, Amiloride, or Hydrocholorthiazide.

5.2. Use with caution in patients taking diuretic medications.

5.3 Keep out of reach of children.

6. ADVERSE REACTIONS

6.1. None known (see CONTRAINDICATIONS for hypersensitivity information).

7. DRUG INTERACTIONS

7.1. None Known

8. USE IN SPECIFIC POPULATIONS

8.1. ***Pregnancy***: Pregnancy category C. Animal reproduction studies have not been conducted with GUNA-DIUR. GUNA®- DIUR should not be given to a pregnant woman.

8.2. ***Lactation***: It is not known whether any of the ingredients in GUNA- DIUR are secreted in human milk. However, since many drugs are secreted in human milk, caution should be exercised when GUNA- DIUR is administered to a nursing woman.

8.3. ***Pediatric use:*** Safety and effectiveness in pediatric patients have not been established.

8.4. ***Geriatric use***: No restrictions.

9. DRUG ABUSE AND DEPENDENCE

9.1. No Known.

10. OVERDOSAGE

10.1. No Known.

11. DESCRIPTION

11. 1 GUNA-DIUR is a homeopathic medicine indicated for the temporary relief of fluid retention, tissue swelling and related disconforts.

12. CLINICAL PHARMACOLOGY

12.1. GUNA-DIUR exerts a diuretic effect. This is based on homeopthica Materia Medica and homeopathic principles.

12.2. Pharmacodynamics
Not applicable to homeopthic medicinal products.

12.3. Pharmacokinetics

Not applicable to homeopthic medicinal products.

13. NONCLINICAL TOXICOLOGY

13.1. Not available.

14. CLINICAL STUDIES

14.1. GUNA-DIUR efficacy is not supported by clinical studies. It is based on homeopathic Materia Medica and scientific literature.

15. REFERENCES

15.1. H.H. Reckeweg. Homeopathic Materia Medica. Aurelia Verlag.
15.2. Boericke, William, Materia Medica with Reperatory, 1927, ninth edition

16. HOW SUPPLIED/STORAGE AND HANDLING

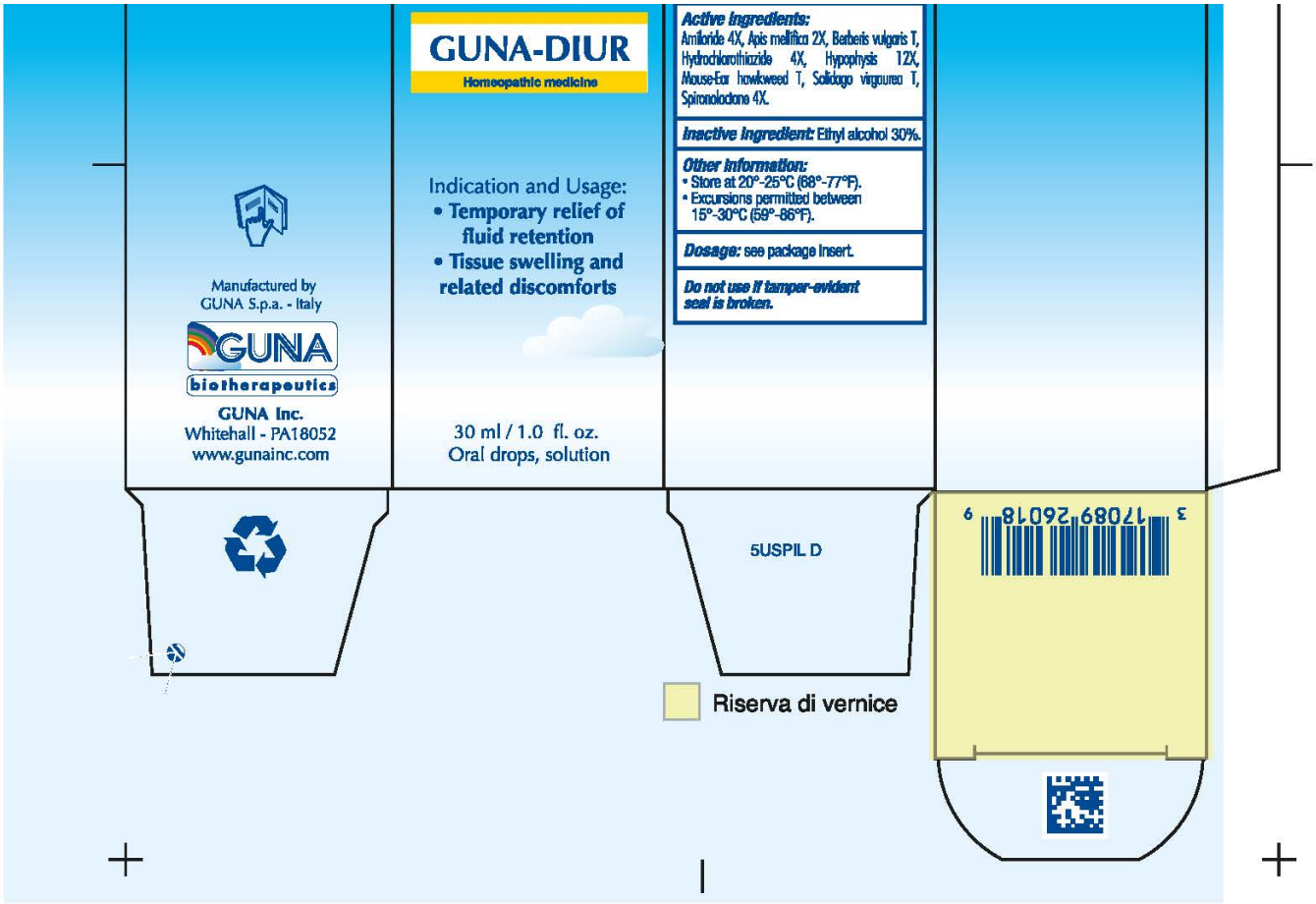
16.1. NDC 17089-260-18 Oral Solution/Drops 30 mL

16.2. Store at 20-25°C (68-77° F). Excursions permitted between 15°-30°C (59°-86°F).

17. PATIENT COUNSELING INFORMATION

17.1. Patients should be informed about Homeopathy and the main differences with conventional clinical approaches.

PACKAGE LABEL



GUNA-DIUR

amiloride - apis mellifera - berberis vulgaris fruit - hieracium pilosella flowering top - hydrochlorothiazide - solidago virgaurea flowering top - spironolactone - sus scrofa pituitary gland - solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:17089-260
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AMILORIDE (UNII: 7DZO8EB0Z3) (AMILORIDE - UNII:7DZO8EB0Z3)	AMILORIDE	4 [hp_X] in 30 mL
APIS MELLIFERA (UNII: 7S82P3R43Z) (APIS MELLIFERA - UNII:7S82P3R43Z)	APIS MELLIFERA	2 [hp_X] in 30 mL
BERBERIS VULGARIS FRUIT (UNII: 6XEF22AHC3) (BERBERIS VULGARIS FRUIT - UNII:6XEF22AHC3)	BERBERIS VULGARIS FRUIT	0.3 g in 30 mL
HYDROCHLOROTHIAZIDE (UNII: 0J48LPH2TH) (HYDROCHLOROTHIAZIDE - UNII:0J48LPH2TH)	HYDROCHLOROTHIAZIDE	4 [hp_X] in 30 mL
SUS SCROFA PITUITARY GLAND (UNII: E8S87O660T) (SUS SCROFA PITUITARY GLAND - UNII:E8S87O660T)	SUS SCROFA PITUITARY GLAND	12 [hp_X] in 30 mL
HIERACIUM PILOSELLA FLOWERING TOP (UNII: 08A7Y81S1P) (HIERACIUM	HIERACIUM PILOSELLA	0.3 g

PILOSELLA FLOWERING TOP - UNII:08A7Y81S1P)	FLOWERING TOP	in 30 mL
SOLIDAGO VIRGAUREA FLOWERING TOP (UNII: 5405K23S50) (SOLIDAGO VIRGAUREA FLOWERING TOP - UNII:5405K23S50)	SOLIDAGO VIRGAUREA FLOWERING TOP	0.3 g in 30 mL
SPIRONOLACTONE (UNII: 27O7W4T232) (SPIRONOLACTONE - UNII:27O7W4T232)	SPIRONOLACTONE	4 [hp_X] in 30 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17089-260-18	1 in 1 BOX	12/21/2018	
1		30 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		05/23/2006	

Labeler - Guna spa (430538264)

Establishment

Name	Address	ID/FEI	Business Operations
Guna spa		338587646	manufacture(17089-260)

Revised: 12/2018 Guna spa