

# stragen

Rx PRODUCTS



## Rx PRODUCTS PORTFOLIO



When the generic drug market is often synonym of blockbuster race and cost cutting, STRAGEN has always been engaged in the development of **Selected and Advanced Generics**.

Thanks to our **30-year R&D know-how**, we constantly aim at improving the existing therapeutics by offering:

- Niche molecules,
- Hard-to-make drugs,
- Innovative delivery forms to improve health daily practices.



## **ORAL** \_\_\_\_\_ 4

We specialize in the development and production management of complex low-concentration hormonal products, niche modified release drugs, and conventional release solid dosage forms.

## **PARENTERAL** \_\_\_\_\_ 9

We develop and manage the manufacturing of high-quality parenteral drugs, such as antibiotics (including Penicillin) and highly potent cytostatic agents.

## **TOPICAL** \_\_\_\_\_ 16

We offer expertise in the development and production of gels and creams.



## ORAL

We specialize in the development and production management of complex low-concentration hormonal products, niche modified release drugs, and conventional release solid dosage forms.



## CARDIOLOGY

### URAPIDIL 30 mg, 60 mg, 90 mg

**Oral use**

Therapeutic Class:  
Antiadrenergic agent –  
peripherally acting

ATC code: C02CA06

Hypertension

Prolonged-release capsule,  
hard Polypropylene bottle with  
polyethylene desiccant cap.

Pack sizes: 30, 50, 60, 90  
and 100 capsules

Shelf life:  
- Climatic Zone II: 24 mths  
- Climatic Zone IV: no data



## GYNAECOLOGY

### CYPROTERONE ACETATE / ETHINYLESTRADIOL 2 mg/0.035 mg

**Oral use**

Therapeutic Class:  
Anti-androgens and oestrogens

ATC code: G03HB01

Severe acne

Coated tablet  
PVC-Aluminium blister strip with 21 tablets

Pack sizes: 1x 21, 3x 21, 6x 21 coated tablets

Shelf life / Storage conditions:  
- Climatic Zone II: 36 mths  
- Climatic Zone IV: 36 mths  
in Aluminium pouch



### DESOGESTREL 75 µg

**Oral use**

Therapeutic Class:  
Hormonal contraceptives for systemic use

ATC code: G03AC09

Oral contraception

Film-coated tablet  
PVC/PVDC-Aluminium blister strip with 28 film-coated tablets

Pack sizes: 1x 28, 3x 28, 6x 28 film-coated tablets

Shelf life:  
- Climatic Zone II: 36 mths  
- Climatic Zone IV: 24 mths



### DESOGESTREL / ETHINYLESTRADIOL 150 µg/20 µg, 150 µg/30 µg

**Oral use**

Therapeutic Class:  
Hormonal contraceptives for systemic use

ATC code: G03AA09

Oral contraception

Tablet  
PVC-Aluminium blister strip with 21 tablets  
in Aluminium pouch

Pack sizes: 1x 21, 3x 21 and 6x 21 tablets

Shelf life:  
- Climatic Zone II:  
30 mths (150 µg / 20 µg)  
36 mths (150 µg / 30 µg)  
- Climatic Zone IV:  
36 mths



## GYNAECOLOGY

### DIENOGEST 2 mg

**Oral use**

Therapeutic Class:  
Progestogens

ATC code: G03DB08

Treatment of endometriosis

Film coated tablet  
PVC-Aluminium blister strips with 14 tablets  
Pack sizes: 2x 14, 6x 14 tablets

Shelf life:  
- Climatic Zone II: 30 mths  
- Climatic Zone IV: 30 mths



### DROSPIRENONE / ETHINYLESTRADIOL 3 mg/0.03 mg

**Oral use**

Therapeutic Class:  
Hormonal contraceptives for systemic use

ATC code: G03AA12

Oral contraception

Film-coated tablet  
PVC-Aluminium blister strips with 21 tablets  
Pack sizes: 1x 21, 3x 21, 6x 21 film-coated tablets

Shelf life:  
- Climatic Zone II: 36 mths  
- Climatic Zone IV: 36 mths



### GESTODENE / ETHINYLESTRADIOL 75 µg/20 µg, 75 µg/30 µg

**Oral use**

Therapeutic Class:  
Hormonal contraceptives for systemic use

ATC code: G03AA10

Oral contraception

Coated tablet  
PVC-Aluminium blister strip with 21 tablets

Pack sizes:  
1x 21, 3x 21, 6x 21 tablets

Shelf life / Storage conditions:  
- Climatic Zone II: 36 mths  
- Climatic Zone IV: 36 mths  
in Aluminium pouch



### GESTODENE / ETHINYLESTRADIOL 60 µg/15 µg

**Oral use**

Therapeutic Class:  
Hormonal contraceptives for systemic use

ATC code: G03AA10

Oral contraception

Film-coated tablet  
PVC-Aluminium blister strip with 24 + 4 tablets

Pack sizes: 1x 28, 3x 28, 6x 28 tablets

Shelf life:  
- Climatic Zone II: 36 mths  
- Climatic Zone IV: 24 mths



## GYNAECOLOGY

### NOMEGESTROL ACETATE 5 mg

**Oral use**

Therapeutic Class: Progestogens

ATC code: G03DB04

Treatment of menstrual cycle disorders due to absence or low secretion of progesterone in premenopausal women. In postmenopausal women as hormone replacement therapy (HRT) for estrogen deficiency symptoms in combination with estrogens.

Breakable tablet

PVC-Aluminium blister strip with 10 or 14 tablets

Pack sizes: 10, 30, 42, 60, 84 and 90 tablets

Shelf life / Storage conditions:

- Climatic Zone II: 36 mths
- Climatic Zone IV: 24 mths in Aluminium pouch



## HORMONE DISORDERS

### CYPROTERONE ACETATE 50 mg

**Oral use**

Therapeutic Class: Antiandrogens

ATC code: G03HA01

Control of libido in severe hypersexuality and/or sexual deviation in the adult male. Treatment of prostate cancer.

Tablet

PVC-Aluminium blister strip with 10/28 tablets

Pack sizes: 10, 20, 56, 84 and 168 tablets

Shelf life:

- Climatic Zone II: 36 mths
- Climatic Zone IV: 36 mths



## ONCOLOGY

### CYPROTERONE ACETATE 50 mg, 100 mg

**Oral use**

Therapeutic Class: Antiandrogens

ATC code: G03HA01

Prostatic cancer

Tablet

PVC-Aluminium blister strip with 10/28 tablets (CPA50) and 10/12 tablets (CPA100)

Pack sizes: 10, 20, 56, 84 and 168 tablets

Shelf life:

- Climatic Zone II: 36 mths
- Climatic Zone IV: 24 mths





## PHLEBOLOGY

### DIOSMINE 600 mg

#### Oral use

Therapeutic Class:

Cardiovascular system – capillary stabilizing agent

ATC code: C05CA03

Improvement of symptoms of venous insufficiency of the lower limbs, e.g. heavy legs and pain, complaints resulting from bedsores. Symptomatic treatment of haemorrhoidal crisis.

Tablet

PVC-Aluminium blister strip with 15 tablets

Pack sizes: 15 and 30 tablets

Shelf life:

- Climatic Zone II: 36 mths

- Climatic Zone IV: no data





## **PARENTERAL**

We develop and manage the manufacturing of high-quality parenteral drugs, such as antibiotics (including Penicillin) and highly potent cytostatic agents.





## ANTI-INFECTIVES

### CEFEPIME 1 g, 2 g

#### Intravenous use

Therapeutic Class:  
Other beta-lactam antibacterials,  
4<sup>th</sup> generation cephalosporins

ATC code: J01DE01

Treatment of infections caused by cefepime-susceptible pathogens, such as pneumonia, urinary tract infections, infections of the abdomen including peritonitis, the gall bladder and bile ducts; in patients with bacteraemia and for the empirical treatment of febrile episodes in patients with neutropenia.

Powder for solution for injection / infusion  
Glass vial

Pack sizes: 1 and 10 vials

Shelf life:

- Climatic Zone II: 36 mths
- Climatic Zone IV: no data



### CEFOTAXIME 0.5g, 1g, 2g

#### Intravenous use

Therapeutic Class:  
Other beta-lactam antibacterials;  
3<sup>rd</sup> generation cephalosporins

ATC code: J01DD01

Treatment of severe infections caused by bacteria sensitive to cefotaxime, such as bacterial pneumonia, infections of the kidneys and upper urinary tract, the skin and soft tissues; intra-abdominal infections (including peritonitis); acute bacterial meningitis (especially caused by H. Influenzae, N. meningitis, E. coli, Klebsiella strains); Sepsis.

Powder for solution for injection / infusion  
Glass vial

Pack size: 10 vials

Shelf life / Storage conditions:

- Climatic Zone II: 36 mths
- Climatic Zone IV: 36 mths,  
do not store above 25°C.



### CEFTAZIDIME 250 mg, 500 mg, 1 g, 2 g, 3 g, 6 g

#### Intravenous / Intramuscular use

Therapeutic Class:  
Other beta-lactam antibacterials,  
3<sup>rd</sup> generation cephalosporins

ATC code: J01DD02

Treatment for nosocomial pneumonia; broncho-pulmonary infections in cystic fibrosis; bacterial meningitis; chronic suppurative otitis media and malignant otitis externa; infections of the urinary tract, the skin and soft tissues, the bone and joint; intra-abdominal infections; peritonitis associated with dialysis in patients on CAPD; bacteraemia; neutropenic patients with fever that is suspected to be due to a bacterial infection.

Powder for solution for injection / infusion  
Glass vial

Pack size: 1 and 10 vials

Shelf life / Storage conditions:

- Climatic Zone II: 36 mths
- Climatic Zone IV: 36 mths;  
do not store above 25°C.



## ANTI-INFECTIVES

### CEFTRIAXONE 250 mg, 500 mg, 1 g, 2 g, 10 g

#### Intravenous / Intramuscular use

Therapeutic Class:  
Other beta-lactam antibacterials,  
3<sup>rd</sup> generation cephalosporins

ATC code: J01DD04

Treatment for bacterial meningitis; pneumonia; acute otitis media, intra-abdominal infections; urinary tract infections including pyelonephritis; infections of bones and joints, the skin and soft tissues; gonorrhoea; syphilis; bacterial endocarditis.

Powder for solution for injection / infusion

Glass vial

Pack size: 1 or 10 vials

Shelf life:

- Climatic Zone II: 36 mths
- Climatic Zone IV: 24 mths



### CEFUROXIME 250 mg, 750 mg, 1.5 g

#### Intravenous / Intramuscular use

Therapeutic Class:  
Other beta-lactam antibacterials,  
2<sup>nd</sup> generation cephalosporins

ATC code: J01DC02

Treatment for community acquired pneumonia; acute exacerbations of chronic bronchitis; urinary tract infections including pyelonephritis; soft-tissue infections, intra-abdominal infections; prophylaxis against infection in surgery.

Powder for solution for injection / infusion

Glass vial

Pack size: 10 vials

Shelf life:

- Climatic Zone II: 24 mths
- Climatic Zone IV: 36 mths



### CLOXACILLINE 500 mg, 1 g , 2 g, 10 g

#### Intramuscular / Intravenous use

Therapeutic Class:  
Beta-lactam antibacterials;  
betalactamase resistant penicillins

ATC code: J01CF02

Treatment of infections caused by penicillinase producing staphylococci as skin and soft-tissue infections, endocarditis, osteomyelitis and sepsis.

Powder for solution for injection / infusion

Glass vial

Pack sizes: 1 and 10 vials

Shelf life:

- Climatic Zone II: 36 mths
- Climatic Zone IV: 36 mths



## ANTI-INFECTIVES

### ERYTHROMYCINE 1 g

#### Intravenous use

Therapeutic Class:  
Macrolides, lincosamides  
and streptogramins

ATC code: J01FA01

Treatment of nosocomial pneumonia; skin and soft tissue infections in patients who are hypersensitive to penicillin or where penicillin is unsuitable for other reasons.

Powder for solution for infusion  
Glass vial

Pack size: 1 and 10 vials

Shelf life:

- Climatic Zone II: 36 mths
- Climatic Zone IV: no data



### FLUCLOXACILLINE 1 g, 2 g, 4 g

#### Intravenous / Intramuscular / Intraarticular / Intrapleural use

Therapeutic Class:  
Beta-lactam antibacterials;  
betalactamase resistant penicillins

ATC code: J01CF05

Treatment of acute and chronic infections caused by flucloxacillin-sensitive penicillinase producing staphylococci (with the exception of methicillin-resistant staphylococci (MRSA/MRSE)) in the respiratory tract, of the skin, mucosa and soft tissues as well as of the bones and bone marrow.

Powder for solution for injection / infusion  
Glass vial

Pack sizes:  
1, 5, 10, 25, 50 and 100 vials

Shelf life:

- Climatic Zone II:  
36 mths
- Climatic Zone IV:  
30 mths



### PIPERACILLIN / TAZOBACTAM

#### 2 g/250 mg, 3 g/375 mg, 4 g/500 mg, 12 g/1.5 g, 36 g/4.5 g

#### Intravenous use

Therapeutic Class:  
Beta-lactam antibacterials, penicillins

ATC code: J01CR05

Treatment of severe pneumonia, complicated infections of urinary tract, intra-abdominal, skin and soft-tissue infections (including diabetic foot infections), in patients with bacteraemia, neutropenic patients with fever suspected to be due to a bacterial infection.

Powder for solution for infusion

Pack sizes: 1, 5, 10 and 12 vials

Shelf life / Storage conditions:

- Climatic Zone II: 24 mths;  
do not store above 25°C.
- Climatic Zone IV: 24 mths;  
do not store above 25°C.





## CARDIOLOGY

### AMIODARONE 50 mg/ml

#### Intravenous use

Therapeutic Class:  
Antiarrhythmics (Class III)

ATC code: C01BD01

Treatment of severe rhythm disorders not responding to other therapies or when other treatments cannot be used.

Concentrate for solution for injection / infusion  
3 ml in glass ampoule

Pack sizes: 5 and 10 ampoules

Shelf life / Storage conditions:  
24 mths; store in a refrigerator  
(2°C to 8°C).



### MILRINONE 1 mg/ml

#### Intravenous use

Therapeutic Class:  
Cardiac stimulants excl. cardiac glycosides

ATC code: C01CE02

Short-term treatment of severe congestive  
and acute heart failure.

Concentrate for solution for infusion  
10 ml and 20 ml glass ampoule

Pack sizes: 1, 3, 5 and 10 ampoules

Shelf life:  
- Climatic Zone II: 36 mths  
- Climatic Zone IV: 36 mths



### URAPIDIL 5 mg/ml

#### Intravenous use

Therapeutic Class:  
Antiadrenergic agent –  
peripherally acting

ATC code: C02CA06

Hypertensive emergencies, severe and very  
severe forms of hypertensive disease,  
hypertension resistant to treatment.

Controlled lowering of blood pressure in  
hypertensive patients during and/or after  
surgery.

Possible to overlap acute parenteral therapy  
with changing to continuous treatment with  
oral agents that lower blood pressure; e.g.  
Urapidil Stragen prolonged-release capsules,  
hard 30 mg, 60 mg or 90 mg.

Solution for injection /  
Concentrate for solution for infusion  
5 ml, 10 ml and 20 ml in glass ampoule

Pack size: 5 ampoules

Shelf life / Storage conditions:  
- Climatic Zone II: 36 mths;  
do not store above 30°C.  
- Climatic Zone IV: 18 mths;  
do not store above 30°C.





## EPILEPSY

### LEVETIRACETAM 5 mg/ml, 10 mg/ml, 15 mg/ml

#### Intravenous use

Therapeutic Class: Antiepileptics

ATC code: N03AX14

Monotherapy in the treatment of partial onset seizures with or without secondary generalisation in adults and adolescents from 16 years of age with newly diagnosed epilepsy.

Ready-to-use solution for infusion  
100 ml Nexcel® dual port bag

Pack size: 10 bags

Shelf life:

- Climatic Zone II: 36 mths
- Climatic Zone IV: no data



## GYNAECOLOGY

### ATOSIBAN 7.5 mg/ml

#### Intravenous use

Therapeutic Class:  
Genito urinary system and sex hormones –  
other gynecologicals

ATC code: G02CX01

Indicated to delay imminent pre-term birth  
in pregnant adult women.

Solution for injection /  
Concentrate for solution for infusion  
0.9 ml (6.75 mg) and 5 ml (37.5 mg) in vial

Pack size: 1 vial

Shelf life / Storage conditions:

- Climatic Zone II: 30 mths;  
store in a refrigerator (2°C to 8°C).
- Climatic Zone IV: no data



## HAEMORRHAGE

### TRANEXAMIC ACID 100 mg/ml

#### Intravenous use

Therapeutic Class: Antifibrinolytics

ATC code: B02AA02

Prevention and treatment of haemorrhages  
due to general and local fibrinolysis in adults  
and children.

Solution for injection  
5 ml and 10 ml glass ampoules

Pack size: 5 ampoules

Shelf life:

- Climatic Zone II: 36 mths
- Climatic Zone IV: no data





## ONCOLOGY

### OXALIPLATINE 50 mg, 100 mg

#### Intravenous use

Therapeutic Class: Antineoplastic agent

ATC code: L01XA03

Treatment of metastatic colorectal and stage III (Duke's C) colon cancer in combination with 5-fluorouracil and folinic acid.

Powder for solution for infusion  
Glass vial

Pack size: 1 vial

Shelf life:

- Climatic Zone II: 36 mths
- Climatic Zone IV: no data



### PACLITAXEL 6 mg/ml

#### Intravenous use

Therapeutic Class:  
Antineoplastic agents (taxanes)

ATC code: L01CD01

Treatment of advanced ovarian cancer, node positive and locally advanced or metastatic breast cancer, advanced non-small cell lung carcinoma (NSCLC) and advanced AIDS-related Kaposi's sarcoma (KS).

Concentrate for solution for infusion  
5 ml (30 mg), 16.7 ml (100 mg)  
and 50 ml (300 mg) in glass vial

Pack sizes: 1 and 10 vials

Shelf life / Storage conditions:

- Climatic Zone II: 24 mths;  
do not store above 25°C.
- Climatic Zone IV: 24 mths







## TOPICAL

We offer expertise  
in the development and production  
of gels and creams.



## ANTI-INFLAMMATORY

### DICLOFENAC 1 %

#### Cutaneous use

Therapeutic Class:  
Musculo-skeletal system -  
anti-inflammatory preparations,  
non-steroids for topical use

ATC code: M02AA15

Tendonitis of the upper and lower limbs;  
post-operative and post-traumatic oedema;  
symptomatic treatment of painful  
osteoarthritis of the fingers and knees.

Gel  
Aluminium tube with 50 g and 100 g gel

Pack size: 1 tube

Shelf life:  
- Climatic Zone II: 36 mths  
- Climatic Zone IV: no data



## DERMATOLOGY

### ADAPALENE 1 mg/g

#### Cutaneous use

Therapeutic Class:  
Topical Retinoids for topical use in acne

ATC code: D10AD03

Cutaneous treatment of acne vulgaris in  
which comedones, papules and pustules  
predominate.

Cream  
Aluminium tube with 30, 45, and 60 g cream

Gel  
LDPE tube with 30, 45 and 60 g gel

Pack size: 1 tube

Shelf life:  
- Climatic Zone II: 30 mths  
- Climatic Zone IV: no data





# THE READY-TO-USE MARKETING KIT BY STRAGEN

SCIENTIFIC  
FILES

TRAINING  
MATERIALS

VIDEOS

MEDICAL EVENTS  
& CONGRESSES

To train  
your sales force  
To convince your target  
To create brand  
awareness

IN-STORE  
VISIBILITY

SUPPORT  
FROM KOL

E-VISUAL  
AIDS

SOCIAL  
MEDIA

PRODUCT  
WEBSITE

# stragen

HEALTH PRODUCTS DEVELOPMENT 

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MEET US AT CPhI 2019

# STRAGEN

is pleased to meet you each year at the CPhI Worldwide®.



SAVE THE DATE:  
**5-7 NOVEMBER 2019**  
FRANKFURT, GERMANY

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