

DEMANDE D'AUTORISATION DE MISE SUR LE MARCHE

**PROPIONATE DE FLUTICASONE – SALMETEROL BASE
CLL PHARMA**

100 µg / 50 µg (par dose)

250 µg / 50 µg (par dose)

500 µg / 50 µg (par dose)

Poudre pour inhalation en récipient unidose

Module 4

NON CLINICAL STUDY REPORTS

- 4.1 Table of content**
- 4.2 Study reports**
- 4.3 Literature references**

- JUIN 2012 -

CLL PHARMA
Nice Premier Arénas
455 Promenade des Anglais
06 299 NICE
FRANCE

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MODULE 4:

NONCLINICAL STUDY REPORTS

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MODULE 4: NONCLINICAL STUDY REPORTS

4.1 Table of Contents of Module 4

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 - 4.2.3.5.1 Fertility and early embryonic development
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- 4.2.3.6 Local Tolerance

4.2.3.7 Other Toxicity Studies (if available)

4.2.3.7.1 Antigenicity

4.2.3.7.2 Immunotoxicity

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4.2.3.7.7 Other

4.3 Literature References

4.2 Study Reports

4.2.1 Pharmacology

4.2.1.1 Primary Pharmacodynamics

Not applicable.

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4.2.1.1 Primary Pharmacodynamics

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4.2.1.2 Secondary Pharmacodynamics

Not applicable.

Propionate de fluticasone/salmétérol base CLL Pharma
500 µg/50 µg, 250 µg/50 µg, 100 µg/50 µg/dose,
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4.2.1.2 Secondary Pharmacodynamics

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4.2.1.3 Safety Pharmacology

Not applicable.

4.2.1.4 Pharmacodynamic Drug Interactions

Not applicable.

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4.2.1.4 Pharmacodynamic Drug Interactions

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4.2.2 Pharmacokinetics

4.2.2.1 Analytical Methods and Validation Reports (if separate reports are available)

Not applicable.

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4.2.2.1 Analytical Methods and Validation Reports (if separate reports are
available)

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4.2.2.2 Absorption

Not applicable.

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500 µg/50 µg, 250 µg/50 µg, 100 µg/50 µg/dose,
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4.2.2.2 Absorption

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4.2.2.3 Distribution

Not applicable.

4.2.2.4 Metabolism

Not applicable.

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4.2.2.4 Metabolism

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4 2.2.5 Excretion

Not applicable.

4.2.2.6 Pharmacokinetic Drug Interactions (nonclinical)

Not applicable.

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4.2.2.6 Pharmacokinetic Drug Interactions (nonclinical)

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4.2.2.7 Other Pharmacokinetic Studies

Not applicable.

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4.2.2.7 Other Pharmacokinetic Studies

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4.2.3 Toxicology

4.2.3.1 Single-Dose Toxicity (in order by species, by route)

Not applicable.

4.2.3.2 Repeat-Dose Toxicity (in order by species, by route, by duration; including supportive toxicokinetics evaluations)

Not applicable.

4.2.3.3 Genotoxicity

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Not applicable.

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4.2.3.3 Genotoxicity

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4.2.3.4 Carcinogenicity (including supportive toxicokinetics evaluations)

Not applicable.

4.2.3.5 Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluations) (If modified study designs are used, the following sub-headings should be modified accordingly.)

Not applicable.

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4.2.3.5 Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluations) (If modified study designs are used, the following sub-headings should be modified accordingly.)

4.2.3.6 Local Tolerance

Not applicable.

Propionate de fluticasone/salmétérol base CLL Pharma
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4.2.3.6 Local Tolerance

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4.2.3.7 Other Toxicity Studies (if available)

Not applicable.

Propionate de fluticasone/salmétérol base CLL Pharma
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4.2.3.7 Other Toxicity Studies (if available)

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4.3 Literature References

4.3 Literature References

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