

USB - Follow-up cohort of patients with chronic obstructive pulmonary disease treated by Seretide Diskus 500 µg / 50 doses [®]

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General

Identification

Detailed name	Follow-up cohort of patients with chronic obstructive pulmonary disease treated by Seretide Diskus 500 µg / 50 doses [®]
Sign or acronym	USB
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL : 907277

General Aspects

Medical area	Pneumology
Keywords	cohort, Seretide Diskus

Scientific investigator(s) (Contact)

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Unit	Laboratoire GSK

Collaborations

Funding

Funding status	Private
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Details	GSK laboratory
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Governance of the database

Sponsor(s) or organisation(s) responsible	Laboratoire GSK
Organisation status	Private
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)
Database recruitment is carried out by an intermediary	A selection of health care professionals
Database recruitment is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	A sample of 360 investigating general doctor will be formed by simple random sampling using a validated sampling frame. A sample of 120 investigating pneumologists will be formed by simple random sampling using a validated sampling frame. The day of consultation, each doctor will keep a registry of patients treated for OCPD. The investigating doctors will ask, using a medical inclusion questionnaire, the first 2 to 3 patients from the registry, for whom they are initiating a treatment via SERETIDE Diskus 500 µg / 50 doses.
Database objective	
Main objective	Describe the population pursuing SERETIDE Diskus 500 µg / 50 doses within the framework of treating OCPD, the methods for prescribing it and their actual conditions of use (observance in particular) as well as the clinical change in patients. Evaluate the impact of the fixed-dose combinations on objective morbidity and on perceived morbidity of OCPD.
Inclusion criteria	? Patient in whom a treatment via Seretide® Diskus 50 µg / 50 doses is initiated on the day of inclusion ? Patients over the age of 40 years,

? Smokers or ex-smokers (> 15 pack-years)

Population type

Age
Adulthood (25 to 44 years)
Adulthood (45 to 64 years)
Elderly (65 to 79 years)
Great age (80 years and more)

Population covered
Sick population

Gender
Male
Woman

Geography area
National

Detail of the geography area
France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)
2007

Date of last collection (YYYY or MM/YYYY)
01/2011

Size of the database

Size of the database (number of individuals)
[500-1000[individuals

Details of the number of individuals
767

Data

Database activity
Data collection completed

Type of data collected
Clinical data
Declarative data

Clinical data (detail)
Direct physical measures
Medical registration

Declarative data (detail)
Paper self-questionnaire

Presence of a biobank
No

Health parameters studied
Health event/morbidity
Health care consumption and services

Quality of life/health perception

Care consumption (detail)

Hospitalization
Medical/paramedical consultation
Medicines consumption

Procedures

Data collection method

? A doctor characteristics sheet completed at the location of the center? A non-inclusion registry of the patients treated for OPCD that consult during the inclusion period ? An inclusion questionnaire completed by the doctor on D0 ? A follow-up questionnaire completed by the doctor at each naturalistic follow-up visit throughout the entire duration of the study? A self-questionnaire completed by the patient at the inclusion visit ? A self questionnaire completed by the patient at each naturalistic follow-up visit throughout the entire duration of the study? A questionnaire on the latest news for patients who left the study during follow-up

Participant monitoring

Yes

Details on monitoring of participants

During follow-up, investigating doctors at 3, 6, 9 and 12 months (+/- 15 days) will question included patients using a medical follow-up questionnaire and will give them a self-questionnaire to be completed independent to the investigator doctor after each follow-up visit.

Links to administrative sources

No

Promotion and access

Promotion

Link to the document

<http://tinyurl.com/Pubmed-USB>

Description

List of publications in Pubmed

Access

Terms of data access (charter for data provision, format of data, availability delay)

Publications in progress

Access to aggregated data

Access on specific project only

Access to individual data

Access on specific project only