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

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Last update : 04/06/2012 | Version : 2 | ID : 164

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
Details	GSK laboratory

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 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 sample 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