
ISR Number: 5942068 Case Number: 6804198 I/F Code: I Report Date: 20081105
Drug Name: **VENTOLIN**
NDA Number: 20983
Role Code: PS VAL/VBM: 1
Seq Number: 1010663758
Mfg. Date: 20081030
Mfg. Number: A0754838A
Mfg. Sender: GLAXOSMITHKLINE
Lot Number:
Expiration Date:
Indication: DRUG USE FOR UNKNOWN INDICATION
Route: UNKNOWN
Dose:
Event Date:
FDA Date: 20081105
Follow Number:
Image ID: 5942068-7
Age: Gender: F Weight:
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: Y Mfg. Notified: Confidential:
Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ALOPECIA
ANGINA PECTORIS
CHILLS
CHOKING
COUGH
DRUG INEFFECTIVE
MALAISE
PAIN

ISR Number: 5946977 Case Number: 6813206 I/F Code: I Report Date: 20081106
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010681080
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication: ASTHMA
Route: OTHER
Dose: 2 PUFFS 4-6 HOURS OTHER
Event Date: 20081105
FDA Date: 20081107
Follow Number:
Image ID: 5946977-4
Age: 40 YR Gender: F Weight: 130 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: N Rechallenge Code: Y Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
 DRUG EFFECT DECREASED
 MALAISE
 PRODUCT QUALITY ISSUE

ISR Number: 5954219 Case Number: 6818435 I/F Code: I Report Date: 20081103
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010708458
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 8ZP3198 CURRENT CANISTER
Expiration Date: 20090601
Indication: MULTIPLE ALLERGIES
Route:
Dose: 18 G -200 METERED DOSES 2 PUFF EVERY 4 HRS. OR AS NEEDED
Event Date: 20081015
FDA Date: 20081113
Follow Number:
Image ID: 5954219-9
Age: 75 Gender: F Weight: 150 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: RI Dechallenge Code: Rechallenge Code: Y Death Date:
Therapy Start:
Therapy End: 20080501
Duration:
Adverse Reactions:
 DEVICE MALFUNCTION
 DRUG EFFECT DECREASED

ISR Number: 5972560 Case Number: 6826983 I/F Code: I Report Date: 20081201

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1010775138

Mfg. Date: 20081118

Mfg. Number: B0548104A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: BRONCHIOLITIS

Route: UNKNOWN

Dose: 3UNIT PER DAY

Event Date:

FDA Date: 20081201

Follow Number:

Image ID: 5972560-0

Age: 23 MON Gender: M Weight: 13 KG

Occupation: CN

Country: FRANCE

Report Source: Electronic Submit: Y Mfg. Notified: Confidential:

Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

- AGGRESSION
- ANGER
- ANOREXIA
- CONVERSION DISORDER
- VOMITING

ISR Number: 5982959 Case Number: 6848642 I/F Code: I Report Date: 20081203
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010808603
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 8XP0829
Expiration Date: 20091031
Indication: ASTHMA
Route:
Dose: 2 PUFFS 4 TIMES DAILY
Event Date: 20081201
FDA Date: 20081205
Follow Number:
Image ID: 5982959-4
Age: 48 YR Gender: F Weight: 230 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N
Outcome Code: OT Dechallenge Code: D Rechallenge Code: D Death Date:
Therapy Start: 20081201
Therapy End: 20080801
Duration: 4 MON
Adverse Reactions:
CHEST PAIN
DRUG INEFFECTIVE
MUSCULOSKELETAL CHEST PAIN
PRODUCT QUALITY ISSUE

ISR Number: 5988631 Case Number: 6858608 I/F Code: I Report Date: 20081205
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010823540
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 8ZP3162
Expiration Date: 20090130
Indication: VIRAL INFECTION
Route: OTHER
Dose: 2 PUFFS AS NEEDED 4-6 HOURS OTHER
Event Date: 20080601
FDA Date: 20081208
Follow Number:
Image ID: 5988631-9
Age: 15 YR Gender: F Weight: 110 LBS
Occupation: CN
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: N Death Date:
Therapy Start: 20080605
Therapy End: 20080601
Duration: 4 DAY
Adverse Reactions:
COUGH
PRODUCT QUALITY ISSUE

ISR Number: 6000083 Case Number: 6850641 I/F Code: I Report Date: 20081215

Drug Name: **VENTOLIN**

NDA Number: 20983

Role Code: PS VAL/VBM: 1

Seq Number: 1010857403

Mfg. Date: 20081205

Mfg. Number: B0549345A

Mfg. Sender: GLAXOSMITHKLINE

Lot Number: UNKNOWN

Expiration Date:

Indication: DRUG USE FOR UNKNOWN INDICATION

Route: RESPIRATORY (INHALATION)

Dose:

Event Date:

FDA Date: 20081215

Follow Number:

Image ID: 6000083-1

Age: 95 YR Gender: M Weight:

Occupation: PH

Country: FRANCE

Report Source: Electronic Submit: Y Mfg. Notified: Confidential:

Outcome Code: OT Dechallenge Code: Rechallenge Code: Death Date:

Therapy Start:

Therapy End:

Duration:

Adverse Reactions:

DRUG ABUSE

NO ADVERSE EVENT

ISR Number: 6013280 Case Number: 6869863 I/F Code: I Report Date: 20081217
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010894719
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date: 20090630
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: 1 TO 2 PUFFS EVERY 4 HRS OR AS INHAL
Event Date: 20081216
FDA Date: 20081218
Follow Number:
Image ID: 6013280-6
Age: 33 YR Gender: F Weight: 90 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: OT Dechallenge Code: Y Rechallenge Code: D Death Date:
Therapy Start: 20081216
Therapy End: 20081215
Duration:
Adverse Reactions:
 DIZZINESS
 DRUG INEFFECTIVE
 RASH

ISR Number: 6023556 Case Number: 6873463 I/F Code: I Report Date: 20081224

Drug Name: **VENTOLIN HFA**

NDA Number:

Role Code: PS VAL/VBM: 1

Seq Number: 1010936597

Mfg. Date:

Mfg. Number:

Mfg. Sender:

Lot Number: 4153137

Expiration Date: 20090831

Indication: ASTHMA

Route: RESPIRATORY (INHALATION)

Dose: 2 PUFFS TWICE DAILY INHAL

Event Date: 20080810

FDA Date: 20081226

Follow Number:

Image ID: 6023556-4

Age: 46 YR Gender: M Weight: 195 LBS

Occupation: CN

Country: UNITED STATES

Report Source: Electronic Submit: N Mfg. Notified: N Confidential: N

Outcome Code: OT Dechallenge Code: Y Rechallenge Code: Y Death Date:

Therapy Start: 20080901

Therapy End: 20080806

Duration:

Adverse Reactions:

- HEADACHE
- IMPAIRED WORK ABILITY
- MIGRAINE
- NO THERAPEUTIC RESPONSE
- PALATAL DISORDER
- PRODUCT QUALITY ISSUE
- SINUS DISORDER
- SWELLING
- TENDERNESS

ISR Number: 6023672 Case Number: 6874521 I/F Code: I Report Date: 20081228
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010936892
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number:
Expiration Date:
Indication:
Route:
Dose:
Event Date: 20081017
FDA Date: 20081229
Follow Number:
Image ID: 6023672-7
Age: 40 YR Gender: F Weight: 127 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: N Confidential: Y
Outcome Code: HO Dechallenge Code: Rechallenge Code: Death Date:
Therapy Start:
Therapy End:
Duration:
Adverse Reactions:
ASTHMA
DRUG INEFFECTIVE
FEAR
PRODUCT QUALITY ISSUE

ISR Number: 6027424 Case Number: 6877041 I/F Code: I Report Date: 20081230
Drug Name: **VENTOLIN HFA**
NDA Number:
Role Code: PS VAL/VBM: 1
Seq Number: 1010950152
Mfg. Date:
Mfg. Number:
Mfg. Sender:
Lot Number: 8ZP3625
Expiration Date: 20091031
Indication: ASTHMA
Route: RESPIRATORY (INHALATION)
Dose: FOUR SPRAYS DURING 8 HR PERIOD TWICE/FOUR HOUR INHAL
Event Date: 20081230
FDA Date: 20081231
Follow Number:
Image ID: 6027424-3
Age: 41 YR Gender: M Weight: 173 LBS
Occupation:
Country: UNITED STATES
Report Source: Electronic Submit: N Mfg. Notified: Y Confidential: Y
Outcome Code: OT Dechallenge Code: N Rechallenge Code: Y Death Date:
Therapy Start: 20081229
Therapy End: 20081229
Duration:
Adverse Reactions:
ASTHMA
CONDITION AGGRAVATED
PRODUCT QUALITY ISSUE