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Within reach.  
Every day.



**Hikma Pharmaceuticals PLC**  
JP Morgan Healthcare Conference  
January 2021

**hikma.**

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# Hikma is well positioned to deliver sustainable growth

## Over the last three years we have strengthened our base business:



Turned around our Generics business



Strengthened commercial capabilities and improved customer service levels



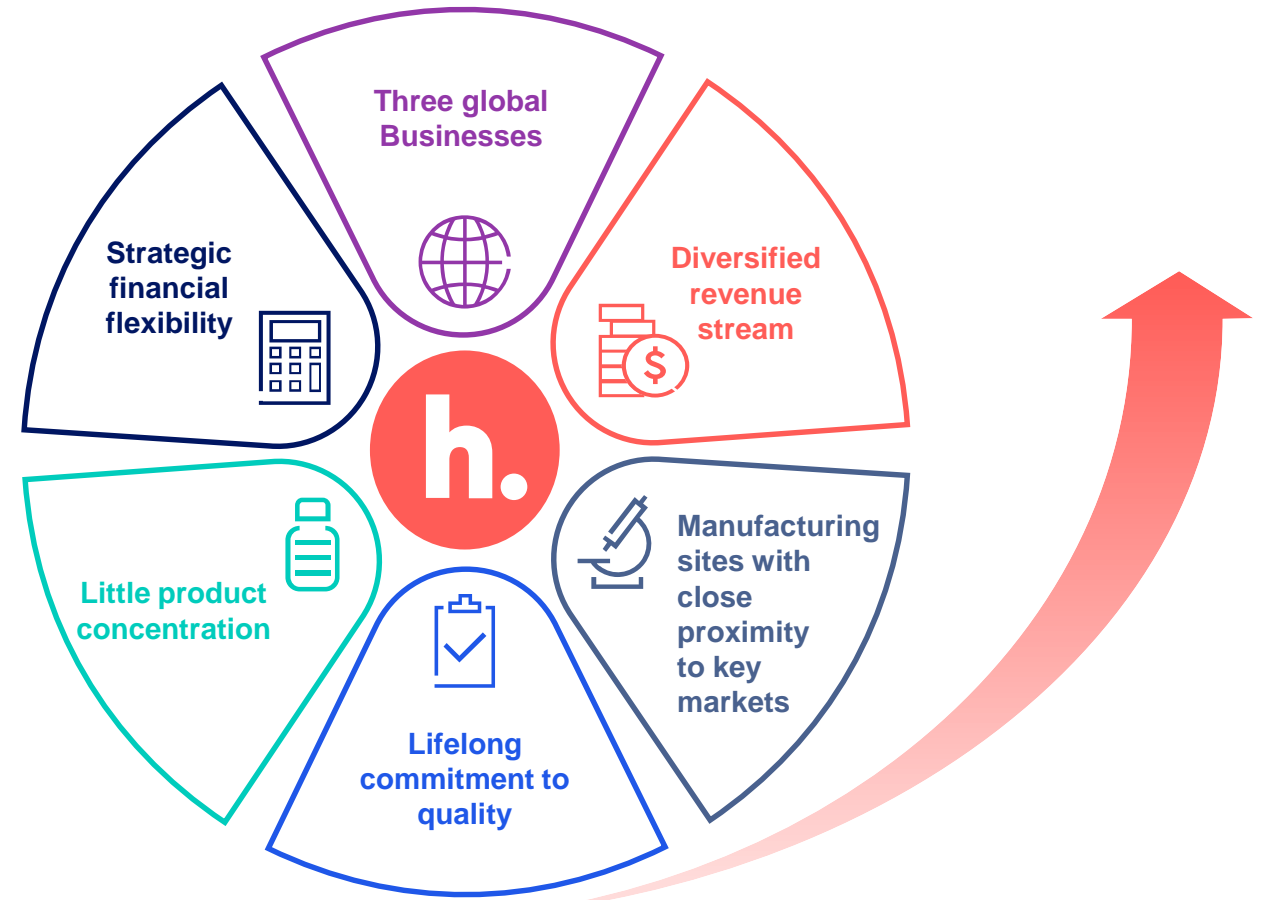
Introduced a focused strategy for MENA and prioritised markets into tier 1 and tier 2



Identified portfolio optimisation and product prioritisation opportunities



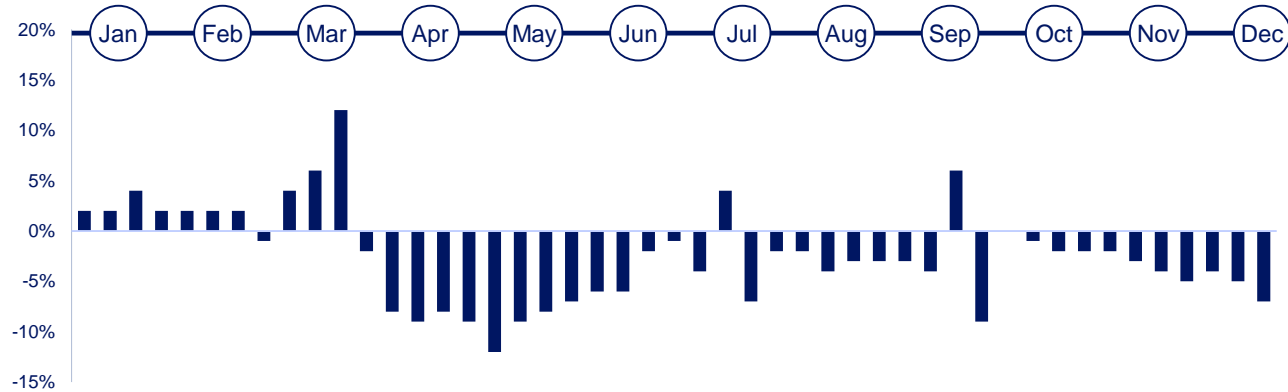
Reduced cost base and improved financial health



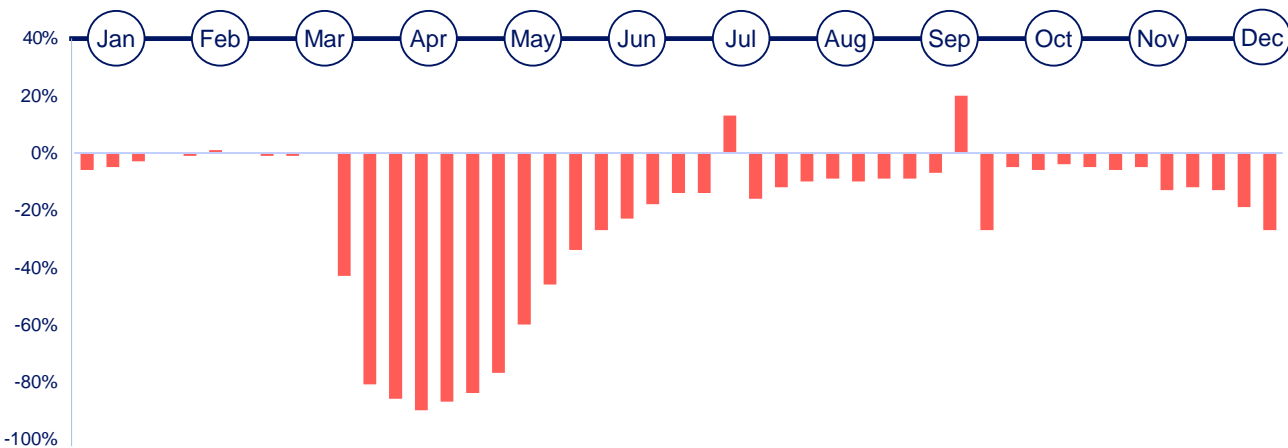
Well positioned to continue growth

# Impact of COVID-19

## Impact of COVID-19 on total prescriptions<sup>1</sup>



## Impact on elective surgeries<sup>1</sup>



## Changing treatment protocols

	% of ICU patients vs. total hospitalized COVID patients	% of ICU patients on mechanical ventilation
April 2020 <sup>2</sup>	30%	82%
December 2020 <sup>3</sup>	23%	54%

## Recent trends

- COVID-19 cases have been rising globally since the Summer slow-down
- Absolute patient numbers in hospitals in the US are higher than the April and July peaks<sup>4</sup>
- Fewer patients are being ventilated relative to earlier peaks; however absolute numbers are increasing as hospital attendance increases

<sup>1</sup> IQVIA data, week on week analysis of data, data week ending November 20, 2020

<sup>2</sup> New York/New Jersey daily hospitalized COVID patient data

<sup>3</sup> TX, AZ, CA, IL, NJ, NY, OH, PA, IN, TN daily hospitalized COVID patient data

<sup>4</sup> <https://ourworldindata.org/covid-hospitalizations>

# Generics



# Generics Segment

Our increasingly differentiated Generics business has seen significant margin improvements



**State of the art** manufacturing facility in Columbus, Ohio



Capabilities in **orals, liquids, nasal, sprays, respiratory, high-containment and controlled substances**

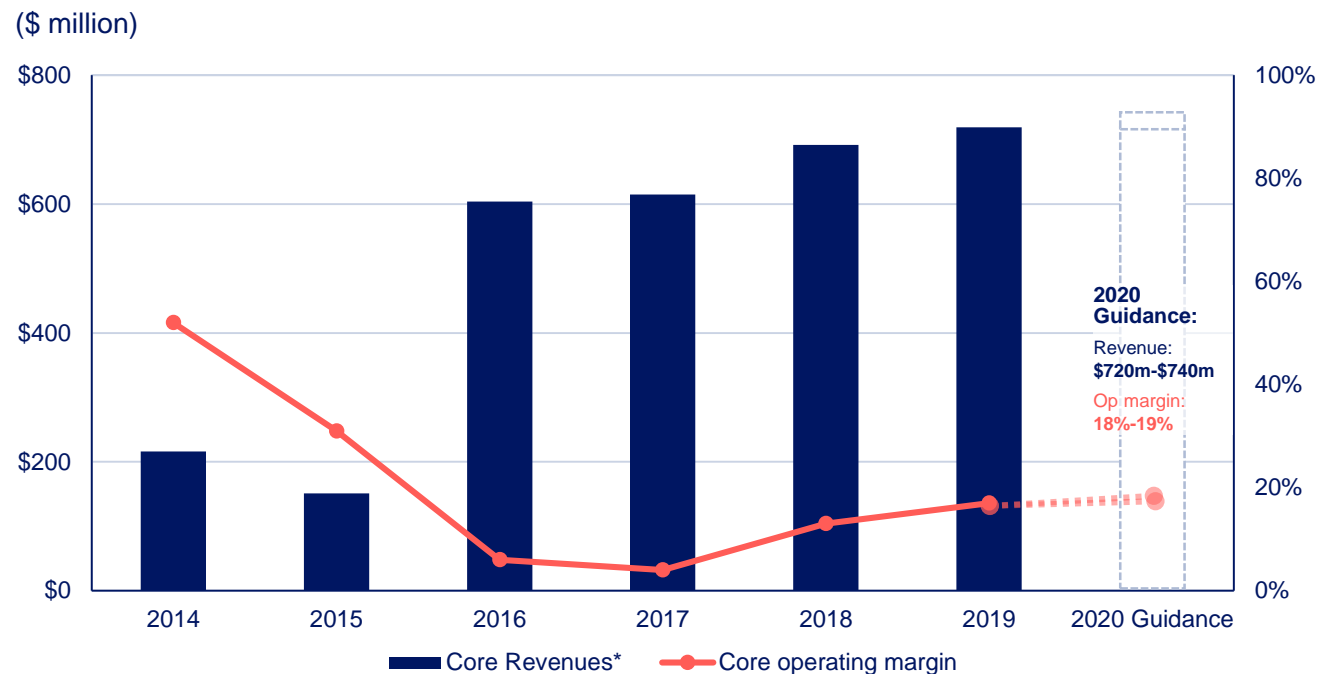


**97 products**



**Over 1,000 employees**

## Generics financial performance



### Recent trends

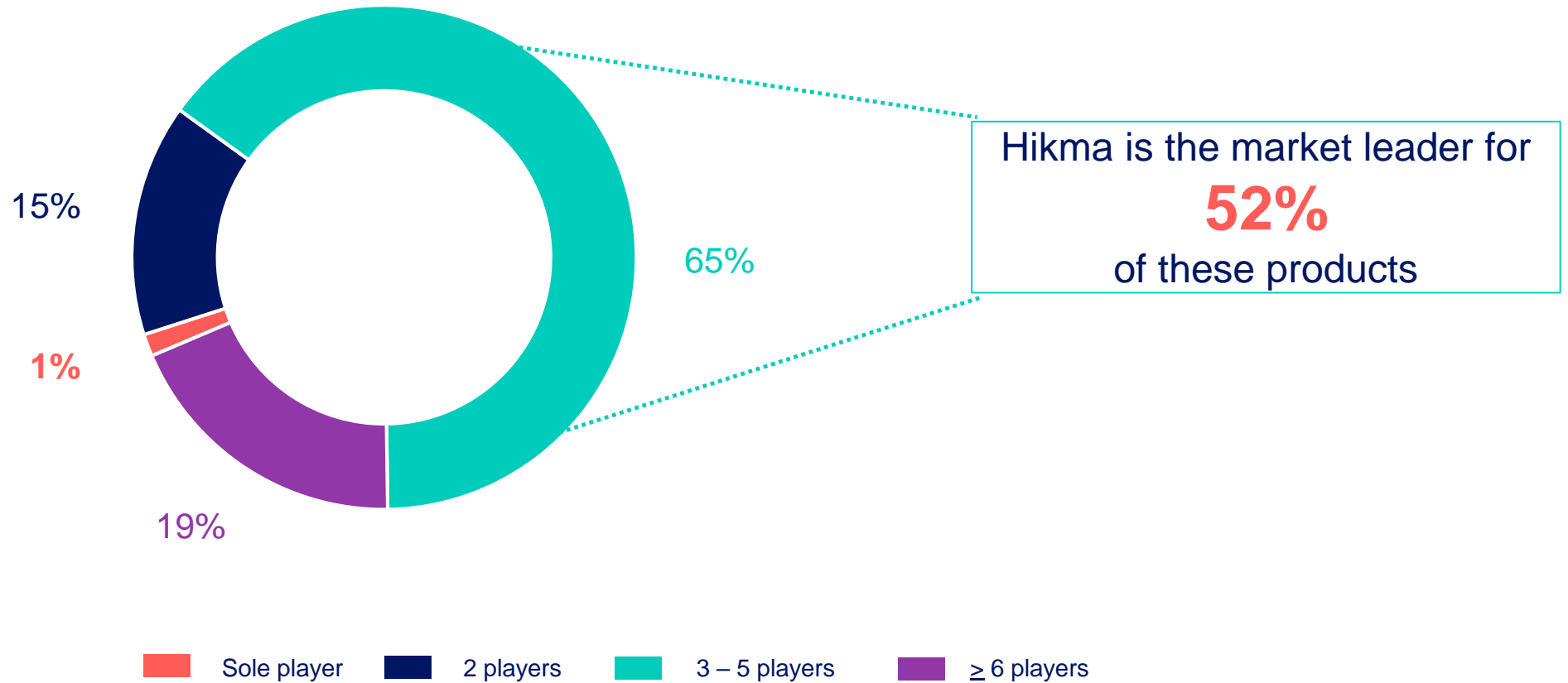
- + Strong demand for differentiated products
- + Better than expected contribution from new launches
- + Some additional demand related to COVID-19
- + Reduced cost base following consolidation of manufacturing and distribution facilities
- Relatively stable pricing in 1H20. Expect price erosion to be in the mid-single digits for the full year in 2020

\*Core results are presented to show the underlying performance of the Group, excluding exceptional items and other adjustments

# Benefitting from diversified portfolio and commercial improvements



## Hikma's Generic portfolio by competition and revenue contribution<sup>1</sup>

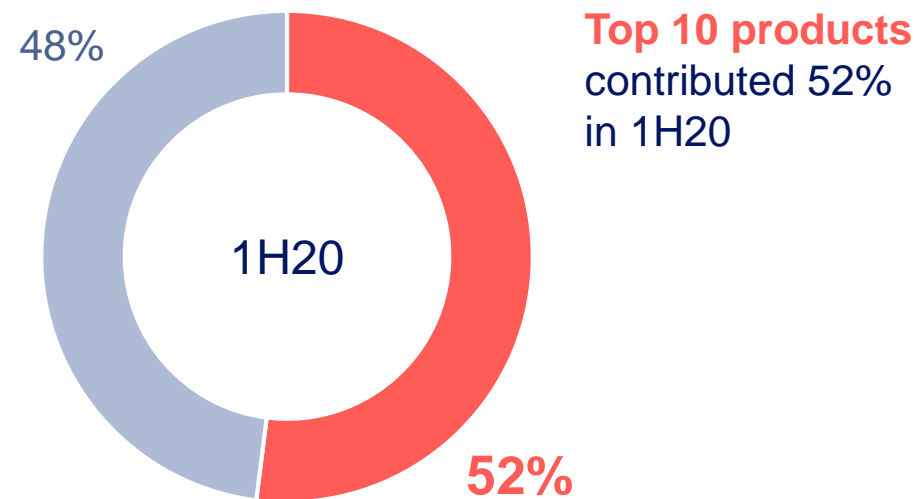
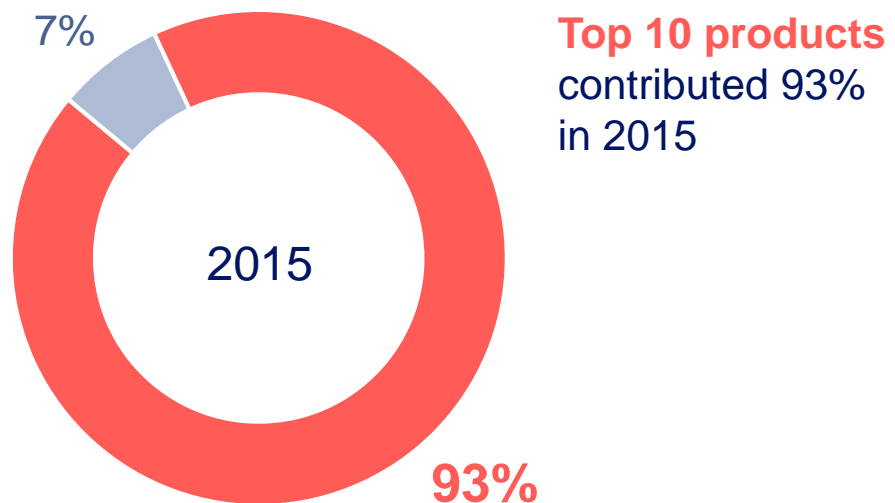


<sup>1</sup> Does not include contract manufacturing

# Optimising our well-diversified portfolio and driving growth through new products



## Generics revenue by product



■ Top 10 products    ■ Other products



# Increasing patients' access to important medicines



2020

2021

Mar

The United States District Court for the District of Nevada finds invalid all asserted patents covering Hikma's icosapent ethyl capsules indication

May

**FDA approves** Hikma's icosapent ethyl capsules

Sep

US Court of Appeals for the Federal Circuit announces **favourable ruling** for Hikma

Nov

Hikma **launches** icosapent ethyl capsules, 1gm in the US

**h.**

Hikma is working to **scale up manufacturing** and **increase availability** of its product

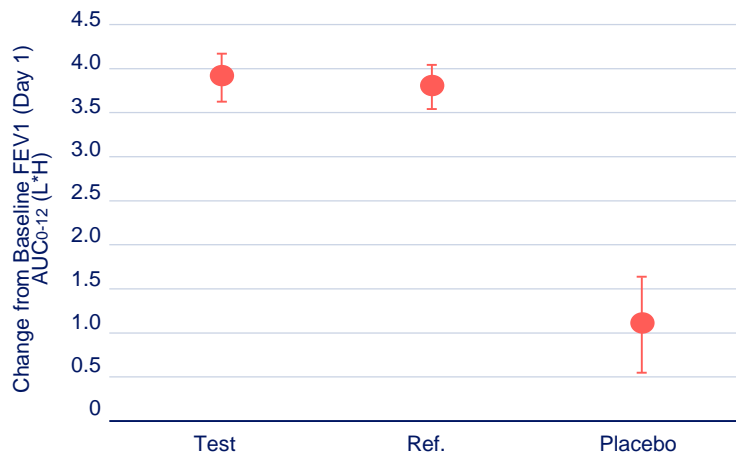
# Received approval for our generic Advair Diskus<sup>®</sup> following our successful clinical endpoint study



**Clinical endpoint study with over 1,500 participants, measuring Forced Expiratory Volume clearly demonstrates clinical equivalence**

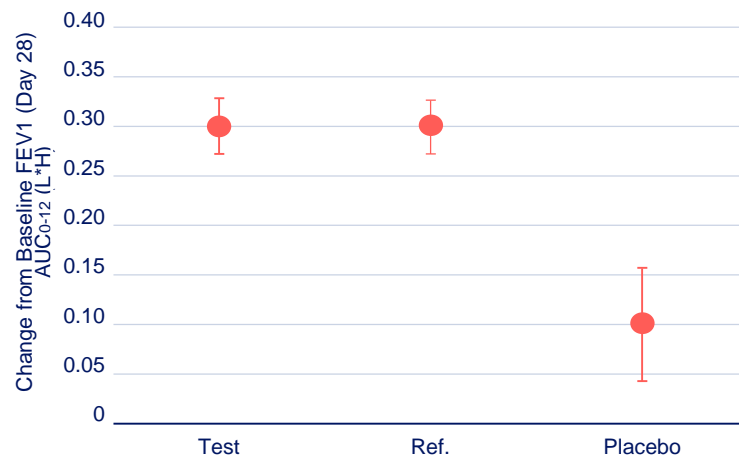
**Mean Change from Baseline in Forced expiratory volume (FEV1) on Day 1 of use\***

Test = Hikma test product  
Ref. = Originator product



**Mean Change from Baseline in Forced expiratory volume (FEV1) on Day 28 of use\***

Test = Hikma test product  
Ref. = Originator product



**Substitutable product with similar operation and usability**

**Hikma device**



**GSK originator device**



\* Study endpoint: (i) Forced expiratory volume (FEV1) calculated from time zero to 12 hours (AUC0-12h) on the first day of the treatment, and (ii) FEV1 measured in the morning prior to the dosing of inhaled medications on the last day of the 4-week treatment

**See included Appendix for indication and safety information about Fluticasone Propionate and Salmeterol Inhalation Powder, USP**

# Injectables



# Injectables Segment

Our leading Injectables business has been steadily growing and has healthy margins



**Top 3** generic Injectables manufacturer in the US



**3** core geographies

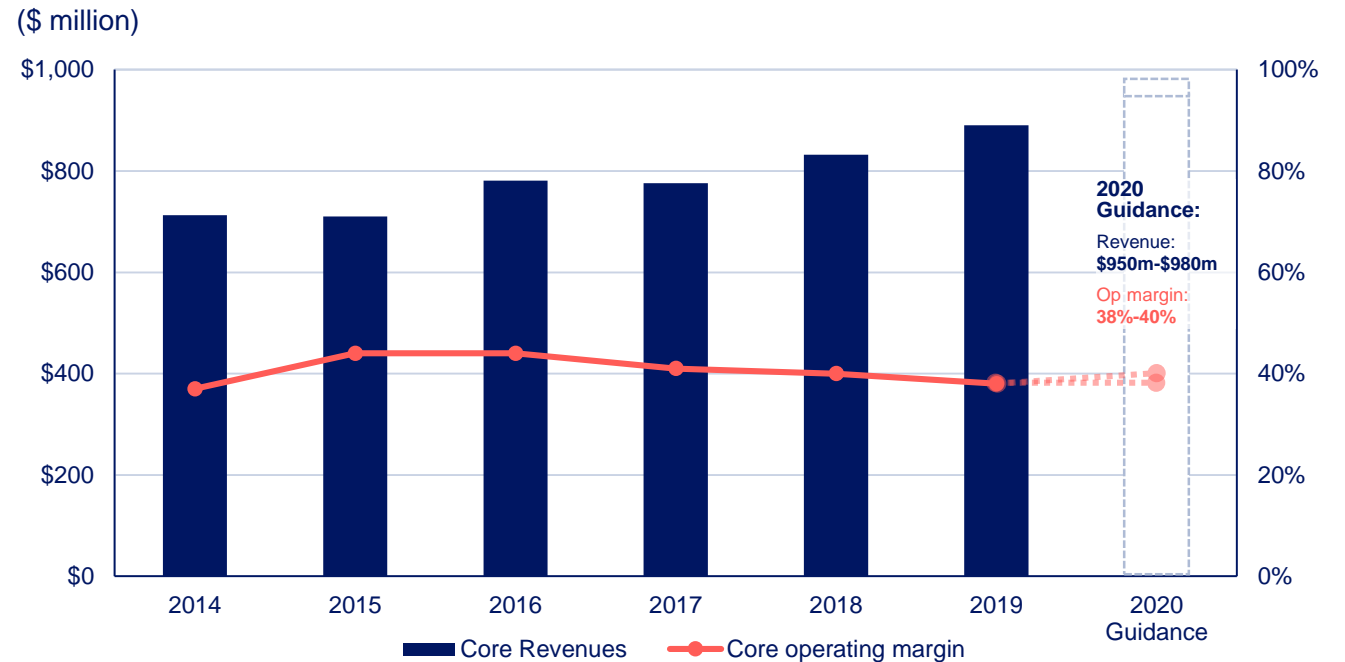


**5** manufacturing facilities around the world



**1 billion** units of annual Injectables manufacturing capacity

## Injectables financial performance



## Recent trends



Increased demand in US and Europe driven in part by COVID-19 in 1Q20



New product launches



Normalising margin driven by changing product, geographic mix and R&D spend



Good growth in MENA with increasing contribution from biosimilars



Increasingly diverse portfolio with less reliance on top products



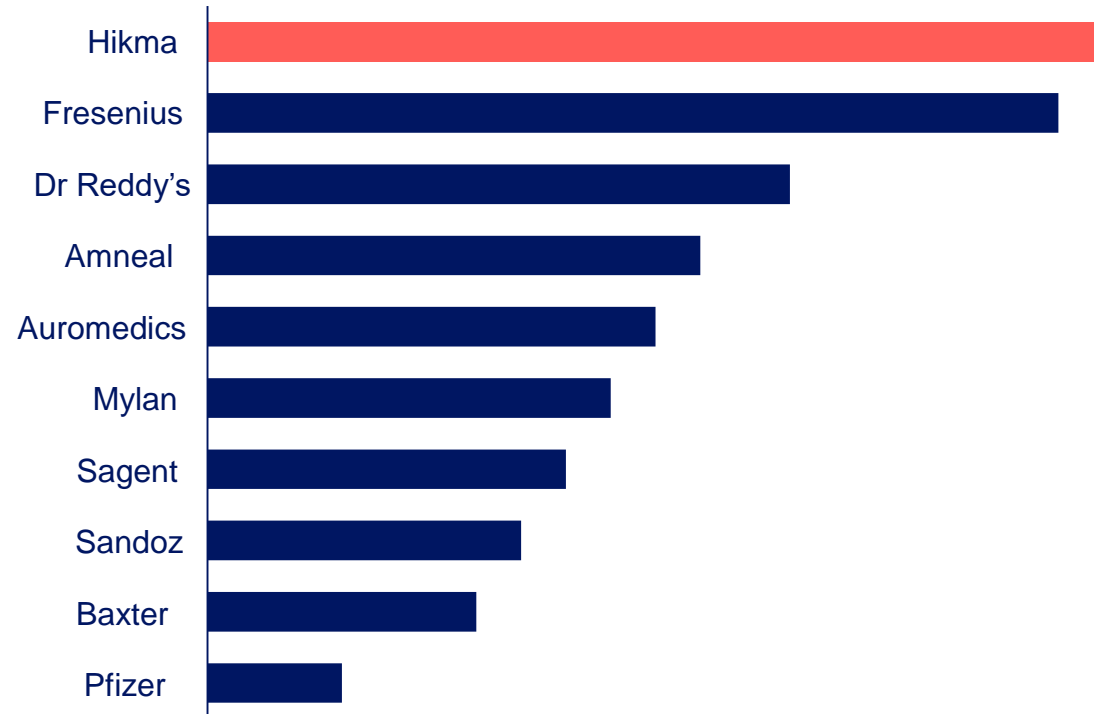
Continue to expect low to mid-single digit price erosion in the US over 2020

# Expanding our US Injectables portfolio and leading in new launches



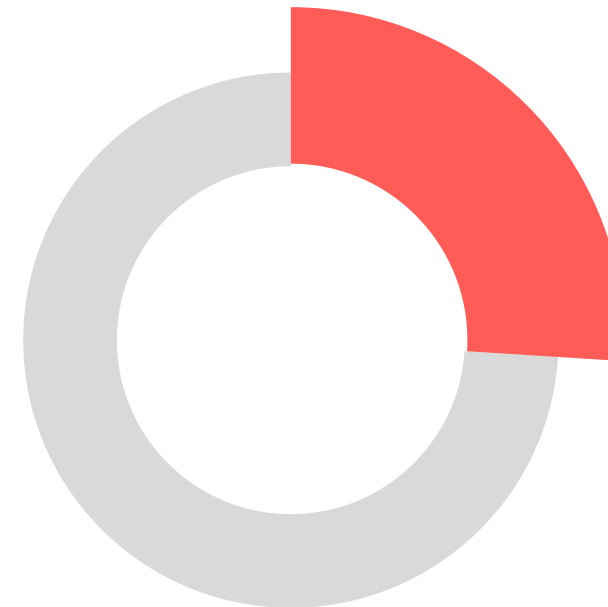
## Number of injectable launched in the US for our key competitors

2019 – 1H20<sup>1,2</sup>



## Contribution from new launches in the US

2016 – 1H20



Products launched since 2016 contributed **26%** of 1H20 US Injectables revenue

<sup>1</sup> Generic launches  
<sup>2</sup> IQVIA US and Hikma internal analysis

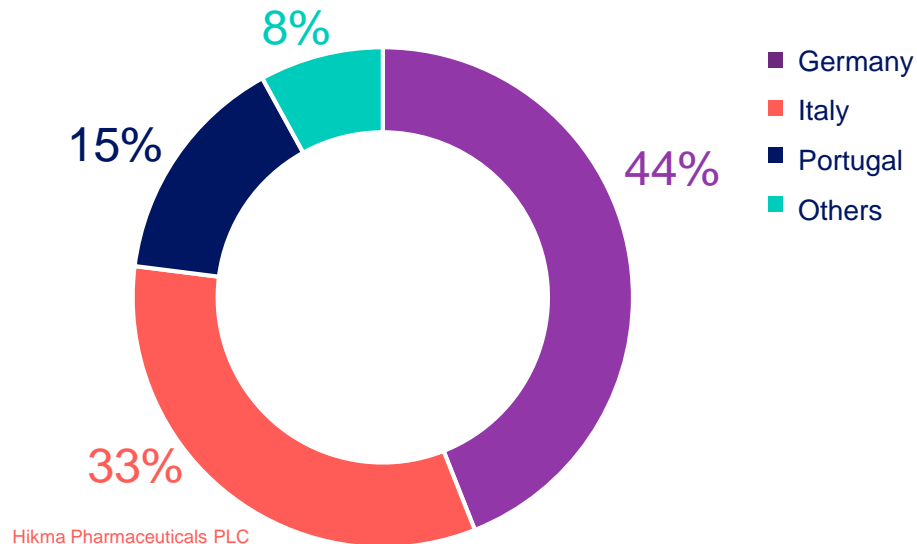
# Strong revenue growth in MENA and Europe



## Europe highlights

- Broad product portfolio supporting COVID-19 patients
- Launching new products across market
- Strong local manufacturing in Portugal, Germany and Italy supporting increased contract manufacturing opportunities
- Expanding into France, Spain and other select markets

## EU Injectables markets by revenue<sup>1</sup>



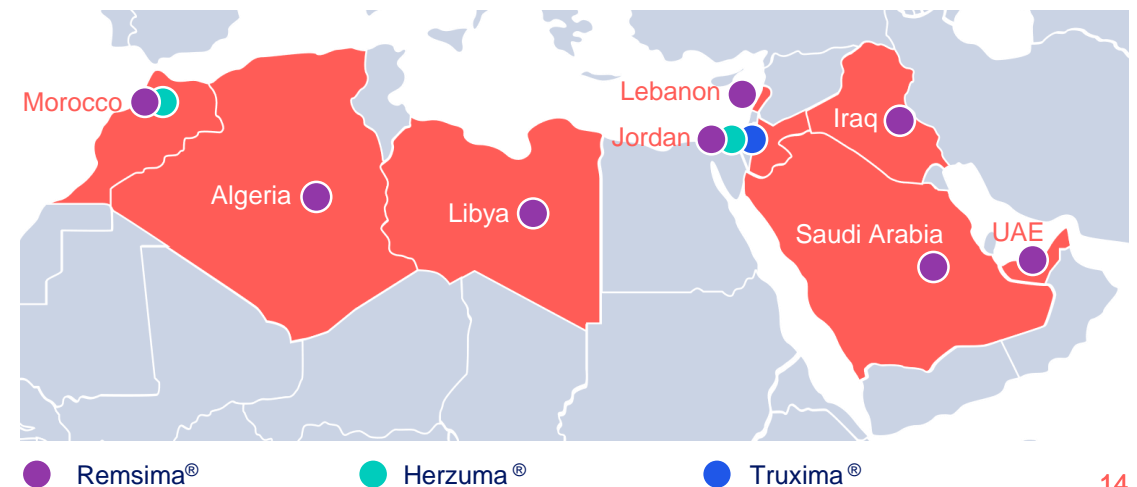
Hikma Pharmaceuticals PLC

<sup>1</sup> Does not include contract manufacturing

## MENA highlights

- Leveraging our broad product portfolio to meet patients' demand
- Continue to drive demand for our biosimilar products
- Launching new products across markets through virtual marketing activities
- In-licensed Ilumya™ from Sun Pharma, an innovative biologic

## Biosimilar launches



# Branded



# Branded Segment

We have a unique Branded business in MENA



**Leading pharmaceutical**  
company in MENA



**Manufacturing facilities in**  
**7 countries**



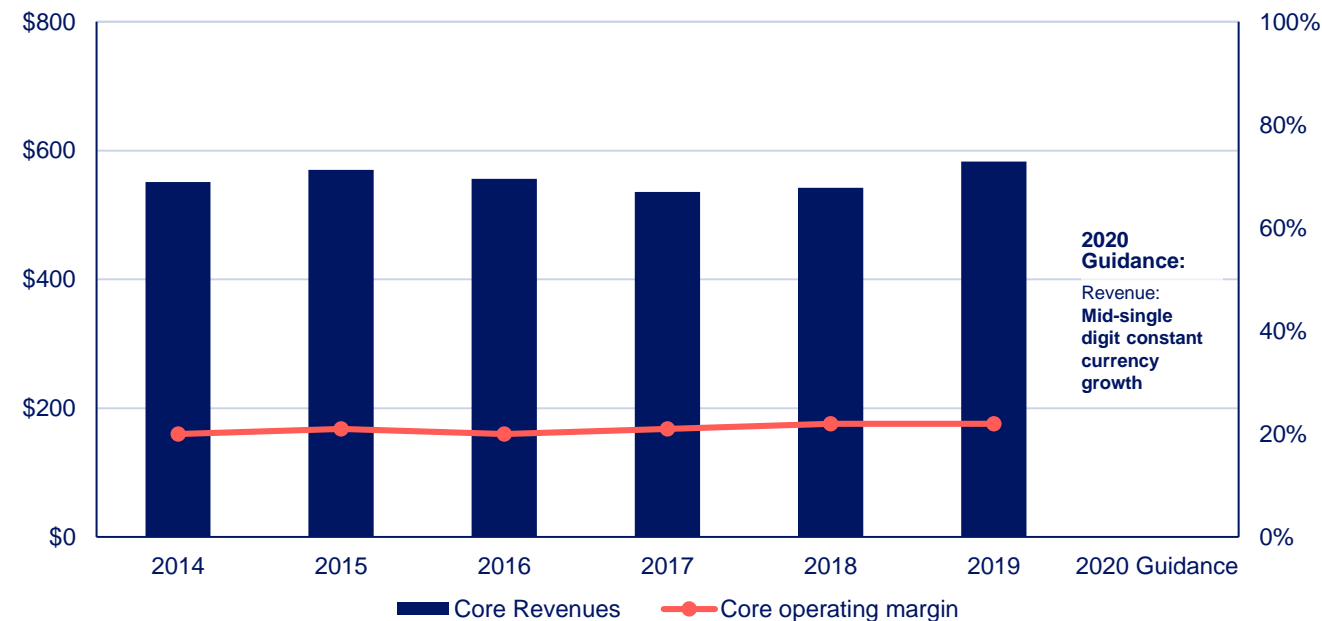
**Large portfolio** of Branded  
generics and in-licensed products



~2,000 sales representatives and  
support staff across 18 markets

## Branded financial performance

(\$ million)



## Recent trends

- + Strong growth in our largest markets, Saudi Arabia and Egypt, as well as Algeria where there has been strong recovery
- + New product launches across all markets

- + Increase in demand in some markets related to COVID-19
- + Accelerating remote promotion
- Minor disruptions in manufacturing facilities due to COVID-19 and expect some currency headwinds



# Delivering growth in tier one markets and leveraging our strong commercial capabilities to increase engagement with stakeholders



Algeria

- + Strong recovery following challenges in 2019 due to political and economic disruptions
- + Improved management of the business



Egypt

- + Good demand for in-market products
- + Initiated launch of in-licensed products from Chiesi



Saudi Arabia

- + Good demand for in-market products
- + Launched 3 new products – Bufomix Easyhaler®, Divinus® and Celect®
- COVID-19 knock-on effect sees reduced demand for certain products such as anti-infectives

## Being proactive in response to COVID-19



Conducting COVID-19 awareness campaigns to assist patients, doctors and pharmacists



Hosted international and local speakers to educate and raise awareness about dealing with different therapeutic areas during COVID-19



Hosted international and local virtual conferences – in Egypt, we hosted 8 international conferences for 300 KOLs and 5 local conferences with 1,500 attendees

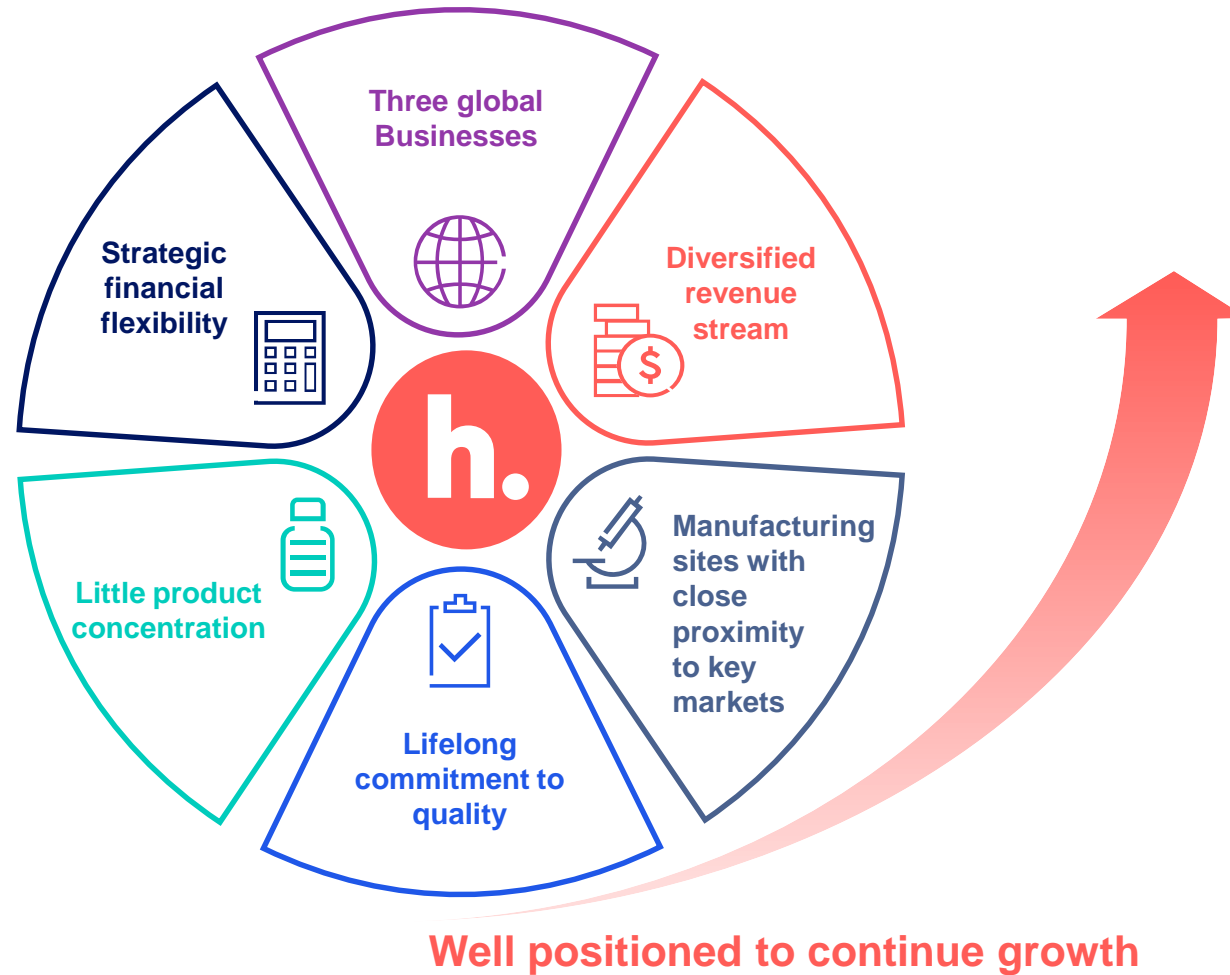


Engaging with governments, food banks and different foundations to help our local community

# Summary



# Hikma is well positioned to deliver sustainable growth



# Appendix



## 2020 guidance

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### Injectables



- Revenue:  
**\$950 million to \$980 million**
- Core operating margin:  
**38% to 40%**

### Generics



- Revenue:  
**\$720 million to \$740 million**
- Core operating margin:  
**18% to 19%**

### Branded



- Revenue growth in constant currency:  
**mid-single digits**

### Net finance expense



- Net finance expense:  
**c.\$47 million**

### Capital expenditure



- Capital expenditure:  
**c.\$120 million**

### Tax



- Core effective tax rate:  
**c.22-23%**

# Important Safety Information for Fluticasone Propionate and Salmeterol Inhalation Powder USP, 100mcg/50mcg, 250mcg/50mcg (1):

## Contraindications

The use of fluticasone propionate and salmeterol inhalation powder is contraindicated in the following conditions:

- Primary treatment of status asthmaticus or other acute episodes of asthma or chronic obstructive pulmonary disease (COPD) where intensive measures are required.
- Severe hypersensitivity to milk proteins or demonstrated hypersensitivity to fluticasone propionate, salmeterol or any of the excipients.

## Warnings and Precautions

### Warnings While Using This Medicine:

Tell your doctor if you are pregnant or breastfeeding, or if you have liver disease, cataracts, diabetes, glaucoma, heart disease, high blood pressure, heart rhythm problems, thyroid problems, seizures, or osteoporosis. Tell your doctor about any immune system problems or infections, including herpes simplex in your eye, tuberculosis, or parasites. Tell your doctor if you have been exposed to chickenpox or measles.

### This medicine may cause the following problems:

Increased risk of asthma-related hospital stays, intubations, and death  
Increased trouble breathing right after use (paradoxical bronchospasm)  
Increased risk of pneumonia in people who have COPD  
Increased risk of infection, including fungus infection in the mouth (thrush)  
Low bone mineral density, which may lead to osteoporosis  
Cataracts, glaucoma, or other vision problems  
Slow growth in children  
Adrenal gland problems

This medicine will not stop an asthma attack that has already started. You should have another medicine to use in case of an acute asthma attack or COPD flare-up. Tell your doctor right away if your condition gets worse or you need to use your other medicine more often than usual.

If any of your asthma medicines do not seem to be working as well as usual, call your doctor right away. Do not change your doses or stop using your medicines without asking your doctor.

Tell any doctor or dentist who treats you that you are using this medicine.

Call your doctor if your symptoms do not improve or if they get worse.

Your doctor will check your progress and the effects of this medicine at regular visits. Keep all appointments.

Keep all medicine out of the reach of children. Never share your medicine with anyone.

### Possible Side Effects While Using This Medicine:

Call your doctor right away if you notice any of these side effects:

Allergic reaction: Itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing

Changes in skin color, dark freckles, easy bruising, muscle weakness, round or puffy face

Chest pain, trouble breathing

Dry mouth, increased thirst, muscle cramps, nausea, vomiting

Eye pain or trouble seeing

Fast, pounding, or uneven heartbeat

Fever, chills, cough, runny or stuffy nose, sore throat, body aches

Tremors, nervousness, or shaking

Unusual tiredness or weakness

Worsening of breathing problems

### If you notice these less serious side effects, talk with your doctor:

Headache

Hoarseness, voice changes

White patches inside the mouth or throat

If you notice other side effects that you think are caused by this medicine, tell your doctor.

Fluticasone propionate and salmeterol inhalation powder contains salmeterol. Long-acting beta<sub>2</sub>-adrenergic agonist (LABA) medicines such as salmeterol when used alone increase the risk of hospitalizations and death from asthma problems. Fluticasone propionate and salmeterol inhalation powder contains an inhaled corticosteroid (ICS) and a LABA. When a fixed-dose combination ICS and a LABA are used together, there is not a significant increased risk in hospitalizations and death from asthma problems compared with ICS alone.

Do not use other medicines that contain a LABA for any reason. Ask your healthcare provider or pharmacist if any of your other medicines are LABA medicines.

Do not use fluticasone propionate and salmeterol inhalation powder to relieve sudden breathing problems. Always have a rescue inhaler with you to treat sudden symptoms.

Do not use fluticasone propionate and salmeterol inhalation powder if you have a severe allergy to milk proteins. Ask your healthcare provider if you are not sure.

Do not use fluticasone propionate and salmeterol inhalation powder if you are allergic to fluticasone propionate, salmeterol or any of the ingredients in fluticasone propionate and salmeterol inhalation powder. Ask your healthcare provider if you are not sure.

Do not use fluticasone propionate and salmeterol inhalation powder more often or at a higher dose than prescribed.

Rinse your mouth with water without swallowing after each dose of fluticasone propionate and salmeterol inhalation powder.

# Important Safety Information for Fluticasone Propionate and Salmeterol Inhalation Powder USP, 100mcg/50mcg, 250mcg/50mcg (2):

## Call your healthcare provider or get medical care right away if:

- your breathing problems get worse. or you need to use your rescue inhaler more often than usual.
- your rescue inhaler does not work as well to relieve your symptoms.
- you need to use 4 or more inhalations of your rescue inhaler in 24 hours for 2 or more days in a row.
- you use 1 whole canister of your rescue inhaler in 8 weeks.
- your peak flow meter results decrease. Your healthcare provider will tell you the numbers that are right for you.
- you have asthma and your symptoms do not improve after using regularly for 1 week

Fluticasone propionate and salmeterol inhalation powder can cause serious side effects, including:

- **Fungal infection in your mouth or throat (thrush).** Rinse your mouth with water without swallowing after each dose of fluticasone propionate and salmeterol inhalation powder.
- **Pneumonia.** People with COPD have a greater chance of getting pneumonia. Fluticasone propionate and salmeterol inhalation powder may increase this risk. Call your healthcare provider right away if you have an increase in mucus (sputum) production, change in mucus color, fever, chills, increased cough or increased breathing problems.
- **Weakened immune system and greater chance of getting infections (immunosuppression).** Fluticasone propionate and salmeterol inhalation powder may make you more prone to infection. Chickenpox and measles, for example, can have a more serious or even fatal course in children or adults using corticosteroids.
- **Reduced adrenal function (adrenal insufficiency).** This can happen when you stop taking oral corticosteroid medicines (like prednisone) and start taking a medicine containing an inhaled steroid (like fluticasone propionate and salmeterol inhalation powder). During this transition period, when your body is under stress such as fever, trauma, infection, surgery or more severe COPD symptoms, adrenal insufficiency can get worse and may cause death. Symptoms of adrenal insufficiency include feeling tired, lack of energy, weakness, nausea and vomiting and low blood pressure.
- **Sudden breathing problems immediately after inhaling your medicine.** If you have sudden breathing problems immediately after inhaling your medicine, stop using fluticasone propionate and salmeterol inhalation powder and call your healthcare provider right away.
- **Serious allergic reactions.** Call your healthcare provider or get emergency medical care right away if you have any of the following symptoms of a serious allergic reaction: rash; hives; swelling of the mouth, face and/or tongue; breathing problems.
- **Effects on the heart.** Call your healthcare provider if you have an increase in blood pressure, fast or irregular heartbeat or chest pain.
- **Effects on the nervous system.** Call your healthcare provider if you have tremor or nervousness.
- **Bone thinning or weakness (osteoporosis).** Get regular bone density screenings if you have or are at risk for osteoporosis treated with established standards of care.
- **Slowed growth in children.** Have your child's growth checked regularly by a healthcare provider while using fluticasone propionate and salmeterol inhalation powder.
- **Eye problems.** Tell your healthcare provider if you have glaucoma, increased pressure in your eye, cataracts or other changes in vision. Get regular eye exams while using fluticasone propionate and salmeterol inhalation powder.
- **Changes in laboratory blood levels (sugar, potassium, certain types of white blood cells).** Get blood tests at your healthcare provider's recommendation.

## Common Side Effects

Common side effects for **asthma include** upper respiratory tract infection, throat irritation, hoarseness and voice changes, thrush in your mouth or throat, bronchitis, cough, headache, and nausea and vomiting. In children with asthma, infections in the ear, nose, and throat are common.

Common side effects for **COPD include thrush** in your mouth or throat, throat irritation, hoarseness and voice changes, viral respiratory infections, headache, and muscle and bone pain.

Common side effects of fluticasone propionate and salmeterol inhalation powder in patients with COPD include thrush in the mouth or throat, throat irritation, hoarseness and voice changes, viral respiratory infections, headache and muscle and bone pain.

These are not all the possible side effects of fluticasone propionate and salmeterol inhalation powder. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

## Drug Interactions

Tell your healthcare provider about all of your medical conditions and about all the medicines you take, as fluticasone propionate and salmeterol inhalation powder can interact with other medicines and may cause side effects, in some cases severe:

## Drugs and Foods to Avoid:

Ask your doctor or pharmacist before using any other medicine, including over-the-counter medicines, vitamins, and herbal products.

Some foods and medicines can affect how fluticasone/salmeterol works. Tell your doctor if you are using any of the following:

Blood pressure medicine

Diuretic (water pill)

Medicine to treat depression or an MAO inhibitor within the past 2 weeks (including nefazodone)

Medicine to treat HIV or AIDS (including atazanavir, indinavir, nelfinavir, ritonavir, saquinavir)

Medicine to treat an infection (including clarithromycin, itraconazole, ketoconazole, telithromycin)

Seizure medicine

## Pregnancy and Breastfeeding

Tell your healthcare provider if you are pregnant, plan to become pregnant or are breastfeeding.

# Important Safety Information for Fluticasone Propionate and Salmeterol Inhalation Powder USP, 100mcg/50mcg, 250mcg/50mcg (3):

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## **Dosage and Administration**

Fluticasone propionate and salmeterol inhalation powder should be administered as 1 inhalation twice daily by the orally inhaled route only. After inhalation, the patient should rinse his/her mouth with water without swallowing to help reduce the risk of oropharyngeal candidiasis.

More frequent use or taking more than 1 inhalation twice daily of the prescribed strength of fluticasone propionate and salmeterol inhalation powder is not recommended.

Do not use additional LABA for any reason.

## **Indications and Usage**

### *Treatment of Asthma*

Fluticasone propionate and salmeterol inhalation powder is indicated for the twice-daily treatment of asthma in patients aged 4 years and older.

### Important Limitation of Use:

Fluticasone propionate and salmeterol inhalation powder is NOT indicated for the relief of acute bronchospasm.

### *Maintenance Treatment of COPD*

Fluticasone propionate and salmeterol inhalation powder 250 mcg/50 mcg is indicated for the twice-daily maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. Fluticasone propionate and salmeterol inhalation powder 250 mcg/50 mcg is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations.

### Important Limitation of Use:

Fluticasone propionate and salmeterol inhalation powder is NOT indicated for the relief of acute bronchospasm.

**For more information about fluticasone propionate and salmeterol inhalation powder, please see the full [Prescribing Information and Medication Guide](#).**

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <https://www.fda.gov/medwatch> or call 1-800-FDA-1088.

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