



# **The use of controller medications in the management of pediatric bronchial asthma - Dynamic patterns of LTRA (montelukast) use**

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## **Abstract**

Over the last few years, bronchial asthma morbidity in pediatric patients has been constantly rising. Asthma is considered the most common disease in adolescents. Our survey was focused on two age groups of pediatric patients: 6 to 12 years old and 13 to 16 years old. It encompassed the period from 2008 to 2013. We examined the use patterns of LTRA (montelukast) and its substantial share of the overall use of asthma controller medications. The results revealed a distinctive upward trend in the use of LTRA (montelukast) in both age groups. The mean absolute growth of montelukast (5 mg) in the group of 6 to 12 years old was 521.6 packs, and the mean growth rate was 333.9%. In the age group of 13 to 16 years old, the mean absolute growth of montelukast (5 mg and 10 mg) was 226.8 packs, and the mean growth rate was 341.3%. Both the drug profile and physicians' propensity to prescribe innovative medicines promote the use of LTRA (montelukast) as an asthma control drug for childhood patients.

## **Key words**

Asthma, Control, LTRA, Montelukast, Use.

## **Introduction**

Over the last several decades, and especially over the last couple of years, asthma morbidity has increased worldwide. According to data provided by WHO, the number of people with asthma in the world is as high as 300 million,

and asthma prevalence in children has been constantly rising [1, 2]. The main purpose of GINA (the Global Initiative for Asthma) is to develop a global strategy for better long-term management of asthma and asthma prevention [3, 4]. The contemporary trends in asthma



management reveal a shift from relievers to controller medications [5, 6, 7, 8, 9]. The patterns in the use of controllers and bronchodilators, as well as the ratio between these two drug groups, are reliable indicators for the quality of asthma treatment and predetermine the therapeutic outcome [10].

Researches focused on the use of asthma controller medications show that leukotriene inhibitors, and in particular – montelukast, constitute a considerable portion of all the administered controller medications [8, 9].

As an alternative to the treatment with inhaled corticosteroids (ICS), leukotriene receptor antagonist (LTRA) can be administered as a monotherapy to patients with mild persistent asthma. Respectively, they can be administered as an adjunctive therapy to pediatric patients with moderate or severe asthma. The administration of leukotriene receptor antagonists facilitates the decrease of inhaled corticosteroids doses [11]. Leukotriene inhibitors suppress asthmatic responses to allergens, exercise, and cold dry air [12].

The treatment of allergic rhinitis with montelukast also shows a good therapeutic outcome. Montelukast is often favoured as a monotherapy for patients with mild to moderate-severe persistent asthma and allergic rhinitis [12].

The profile of montelukast makes this drug the most favoured one for the treatment of respiratory allergies in childhood.

## Objectives

To examine the major drug groups used for the treatment of pediatric asthma and to track the upward trend in the dynamic patterns of montelukast (LTRA) use.

## Material and methods

We performed an analysis of the medicines with montelukast active ingredient used for the treatment of children with asthma. The analysis was based on an exhaustive retrospective study of prescriptions fully or partially reimbursed by the NHIF (National Health Insurance Fund).

Drug use data were collected from a representative sample of 37 community pharmacies in the town of Varna (out of 148 pharmacies in 2013). The selected pharmacies had a cost-reimbursement contract with the NHIF and were situated in town areas with younger population.

The analysis was based on the medicines prescribed to pediatric patients in two age groups (6 to 12 years old and 13 to 16 years old) for the period 2008-2013.

## Results and Discussion

The findings of our survey indicated that the use of asthma controller medications in Bulgaria has been increasing in line with global trends. The increase has affected the group of controller medications as a whole and the separate members of the group alike.

The group of LTRA medicines, immediately followed by ICS, has experienced the most significant increase (total number of packs sold) in the age group 6-12 years. There was a slight increase in the use of ICS/LABA combination drugs in the period 2008 - 2012, followed by a decrease in 2013. There was a slight upward trend in the use of SABA medications as per **Graph – 1.**

The results received in the age group 13-16 years reveal a strong upward trend in the use of LTRA medicines. The group of ICS experiences an uneven upward trend, and the use of ICB/LABA



combination drugs exceeded the use of ICS after 2012. There was a constant upward trend in the use of SABA medications. Still, they are the least prescribed medicines among the surveyed medicines as per **Graph – 2**.

The increase in the use of SABA drugs registered in both age groups implies poor asthma control, more pronounced in the group 13-16 years.

Surveys in the United States, Australia and Europe indicated a change in the medications used to prevent asthma in childhood, with an increase in leukotriene receptor antagonists, inhaled corticosteroids, and long-acting  $\beta$ -agonists [5, 8, 9].

According to the findings of our survey, controller medications constitute the greatest portion of drugs administered for outpatient treatment in both survey groups. Short-acting  $\beta$ -agonist (SABA) hold the modest share in the sales of asthma drugs - 6.06% in the age group 6-12 years, and 9.21% in the age group 13-16 years. The percentage distribution of drugs most frequently used for pediatric asthma treatment as per **Graph – 3** and **Graph - 4**.

According to the findings of our survey, the most frequently used asthma drug was montelukast – 46.01% in the age group 6-12 years, and 50.76% in the age group 13-16 years. The second most-used drugs were the inhaled corticosteroids – 39.74% in the age group 6-12 years, and 21.73% in the age group 13-16 years. The third most-used group of drugs was the group of combined ICS – respectively 8.19% and 18.3%.

The results showed that in general, the prescription patterns follow GINA's recommendations and therapeutic guidelines. The use of short-acting  $\beta$  agonist is confined only to symptom relief when necessary, whereas

controller medications are used for the management of asthma control [4].

There was a distinctive upward trend in the use of LTRA – montelukast. We inferred that the increase of LTRA use is determined by its profile. Montelukast can be used both at the initial stage of a persistent asthma monotherapy (instead of ICS), or as an adjunctive therapy to the treatment with ICS in cases of poor asthma control [4].

The convenience of the oral-route drug administration probably underpins the frequent use of leukotriene antagonists because patients often fail to acquire and maintain adequate inhaler technique as an essential element of the inhaler therapy.

The sales patterns of montelukast (the product with the most clear-cut trend of increase) in both age groups were as per **Table – 1** and **Table - 2**.

In 2013, the absolute growth of montelukast 5 mg in the age group 6-12 years is 806 packages. There had been a steady upward trend in the use of montelukast 5 mg over the period 2008-2013. The mean absolute growth was 521.6 packs, and the mean growth rate was 339.3%.

The use of montelukast 5 mg and 10 mg in the age group 13-16 years had been constantly increasing over the survey period. Its absolute growth for 2013 was 324 packages. The mean absolute growth was 226.8 packs, and the mean growth rate was 341.3%.

Undoubtedly the increased use of montelukast had been underpinned by the implemented government policy on the generic drug use. When the brand-name product faced a patent expiration in 2009, alternative generic medicines with competitive prices entered the market.



Generic drugs are “therapeutically equivalent”, hence assumed to provide therapeutic results equivalent to those of the original product [13].

Cheaper analogues have been NHIF’s favoured choice for reimbursement after the entry of generic drugs. Thus, the treatment costs have been reduced and savings have been allocated for alternative projects. The comparison between the reimbursement patterns of the brand name product and the montelukast generic analogues was as per **Graph - 5**.

We can summarize the factors underpinning the increased use of montelukast sodium in Bulgaria as follows:

- The drug profile and physicians’ propensity to innovative medical products.
- Patent expiration of the brand name product in 2009, followed by the entry of generic products.
- The increased number of consumers as a result from the reduced financial pressure on the health insurance funds, and the improved access to medicines after 2009.

### Conclusion

The survey of asthma drugs administered to pediatric patients found that asthma management complies with the therapeutic guidelines and GINA’s recommendations. The implemented government policy on generic drugs and the generic drugs entry in the pharmaceutical market improve the access to medical products and facilitate the effective management and prevention of asthma.

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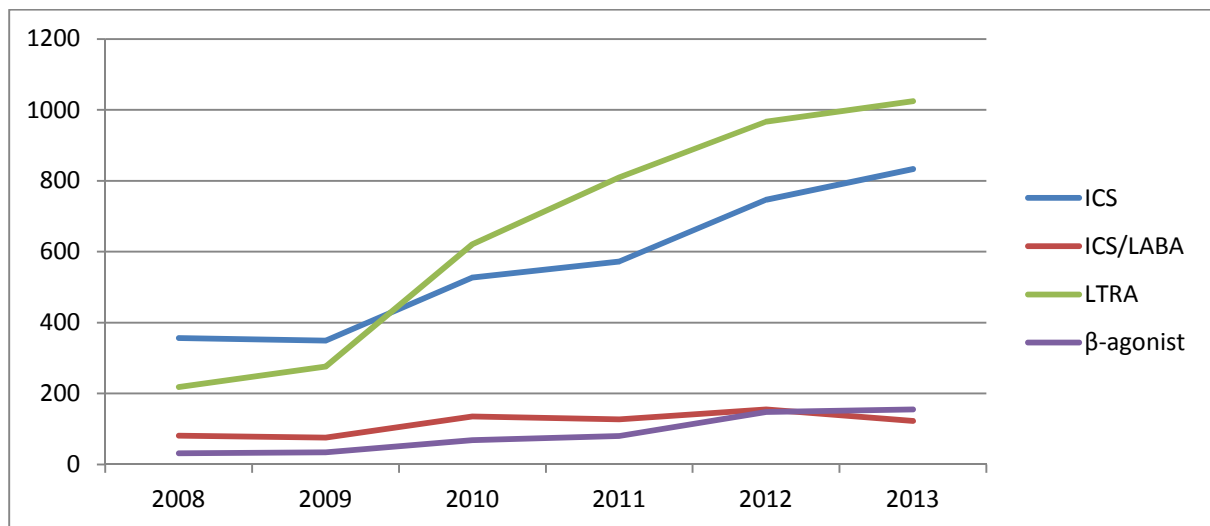


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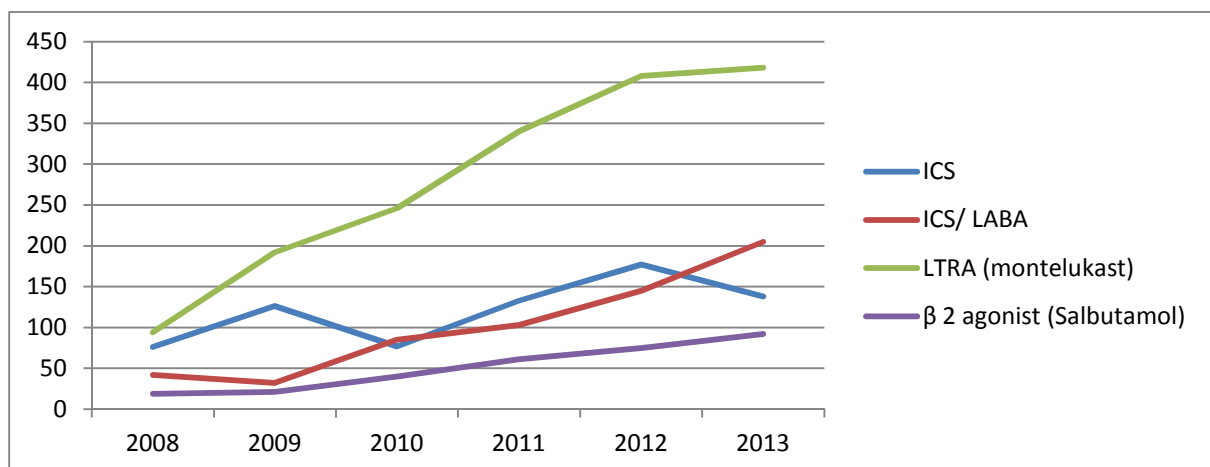
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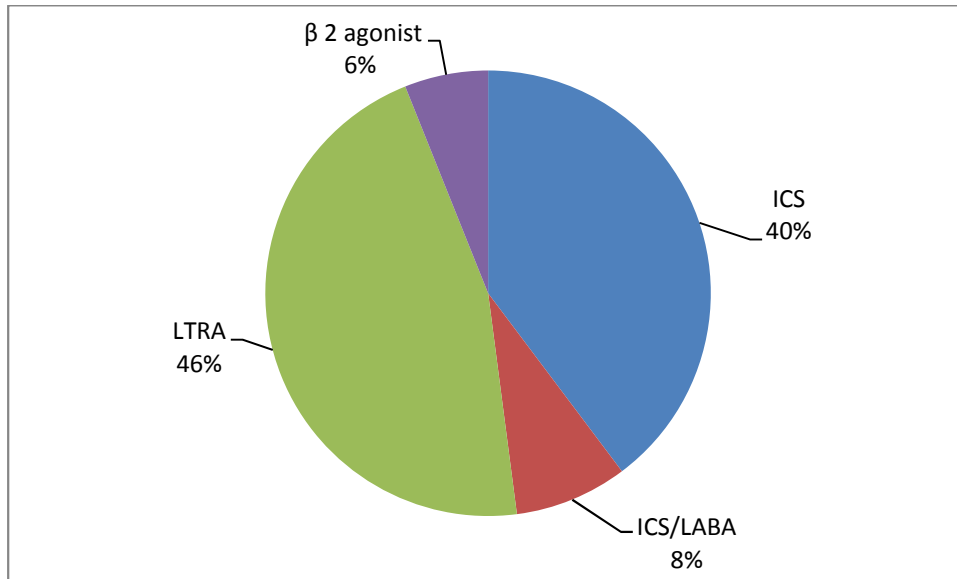
**Graph – 1:** Trends in the use of asthma drugs (number of packs) for the period 2008-2013 in the age group 6-12 years.



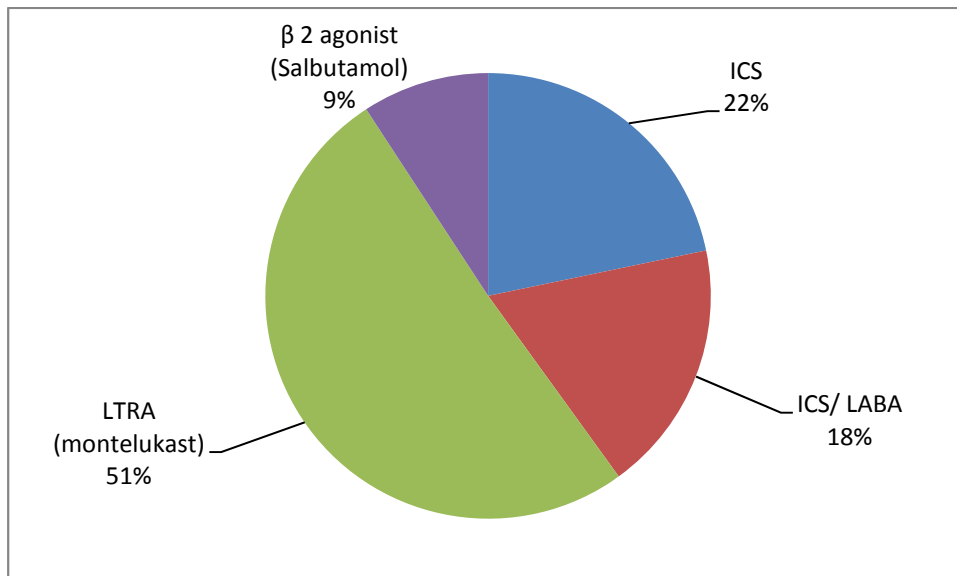
**Graph – 2:** Trends in the use of asthma drugs (number of packs) for the period 2008-2013 in the age group 13-16 years.



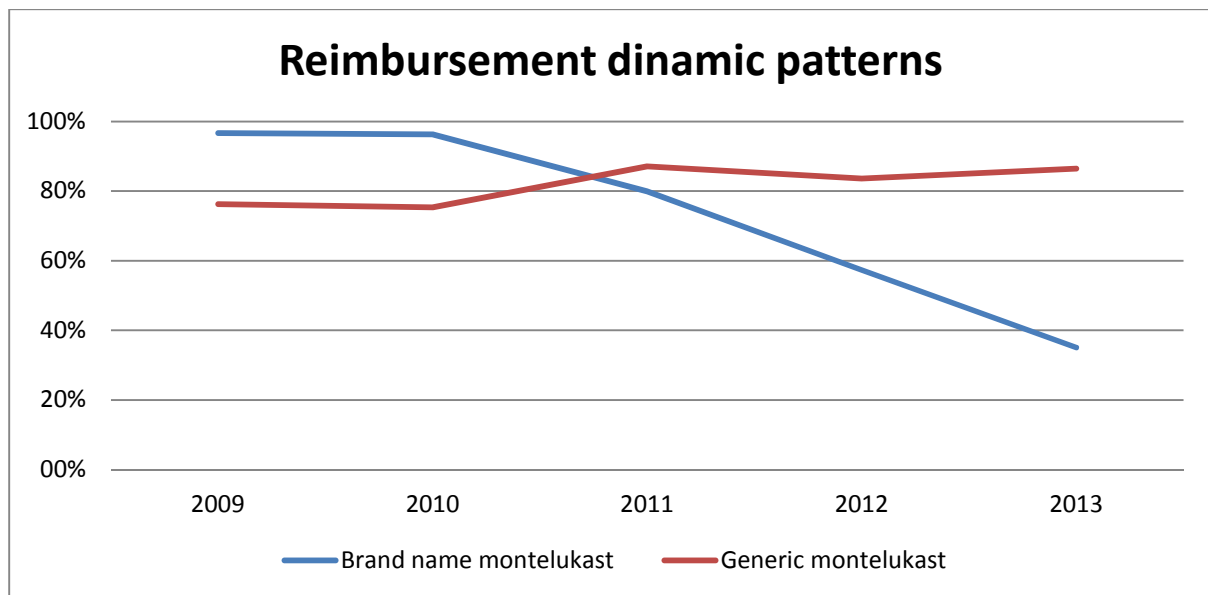
**Graph – 3:** Percentage distribution of drug groups used for asthma treatment in the age group 6-12 years (number of packs).



**Graph – 4:** Percentage distribution of drug groups used for asthma treatment in the age group 13-16 years (number of packs).



**Graph – 5:** Dynamic patterns of reimbursement – brand name montelukast and generic montelukast.



**Table – 1:** Dynamic patterns montelukast (5 mg) use, age group 6-12 years.

Montelukast 5 mg	Total number of packs	Absolute growth	Growth rate
2008	218		
2009	276	58	126.6%
2010	621	403	284.9%
2011	810	592	371.6%
2012	967	749	443.6%
2013	1024	806	469.7%

**Table – 2:** Dynamic patterns montelukast (5 mg/ 10 mg) use, age group 13-16 years.

Montelukast 5 mg /10 mg	Total number of packs	Absolute growth	Growth rate
2008	94		
2009	192	98	204,3%
2010	246	152	261,7%
2011	340	246	361,7%
2012	408	314	434,0%
2013	418	324	444,7%