

# Press release: Blood pressure and heart medication recalled from Pharmacies

Pharmacies in the UK are being advised to recall all batches of valsartan containing medicines made by Dexcel Pharma Ltd and Accord Healthcare (previously known as Actavis Group) as a precaution, the Medicines and Healthcare products Regulatory Agency's (MHRA) has warned today. This follows an urgent investigation in to medicines containing valsartan used to treat high blood pressure and heart conditions.

A recall is underway across Europe following recent and emerging information that an impurity has been identified as part of the manufacturing process in a valsartan active substance manufactured at one facility based in China. This facility has supplied the manufacturers with the valsartan active substance. The impurity (N-nitrosodimethylamine), which may have carcinogenic potential, is a result of a change in the manufacturing process. This active substance is used in a number of medicines marketed in Europe.

The European Medicines Agency and other EU regulators are working together to investigate the extent of the issue and any possible impact for patients.

If you are taking any of the affected valsartan products, it is vital that you do not stop taking your medication but you should get in touch with a doctor or healthcare professional as soon as possible. Alternative valsartan containing products, that are unaffected by this issue, are available in the UK.

Patient safety is our top priority and we will provide further updates as the investigation progresses.

Dr Sam Atkinson, MHRA's Director of the Inspection, Enforcement and Standards Division said:

People taking valsartan medication affected by this recall are advised to not stop taking their medication, but to speak to their doctor or healthcare professional who can advise on alternative treatment.

We continue to undertake an urgent review of all these products that may pose a low risk to public health.

We will communicate the outcome of our investigations and ensure that any other affected products are recalled.

Our highest priority is to ensure that the medicines you take are safe.

If you are concerned, please speak to your GP, pharmacist or other healthcare professional.

We strongly encourage anyone taking Valsartan medicines to report any suspected side effects, to us via our [Yellow Card Scheme](#).

## Notes to Editor

1. MHRA is responsible for regulating all medicines and medical devices in the UK. All our work is underpinned by robust and fact-based judgments to ensure that the benefits justify any risks. MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the [National Institute for Biological Standards and Control \(NIBSC\)](#) and the [Clinical Practice Research Datalink \(CPRD\)](#). The Agency is an executive agency of the Department of Health. [www.mhra.gov.uk](http://www.mhra.gov.uk)
2. [Link to Yellow Card Scheme](#)
3. [MHRA Drug Alerts](<https://www.gov.uk/drug-device-alerts>)

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Office hours are Monday to Friday, 8:30am to 5pm. For real-time updates including the latest press releases and news statements, see our Twitter channel at <https://www.twitter.com/mhrapress>

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# Press release: Recall – SAM XT Extremity Tourniquet

First responders and people who participate in outdoor activities, such as mountaineering and hiking, should check if they have a SAM XT Extremity Tourniquet and return it to their distributor for a new one.

A problem in the sewing operations has been identified which could cause the seam holding the buckle to the belt to fail when used on a patient to stop blood flow. Although not widely used in the UK, tourniquets are used for critical, emergency situations, and so it's important people are aware if they own an affected product.

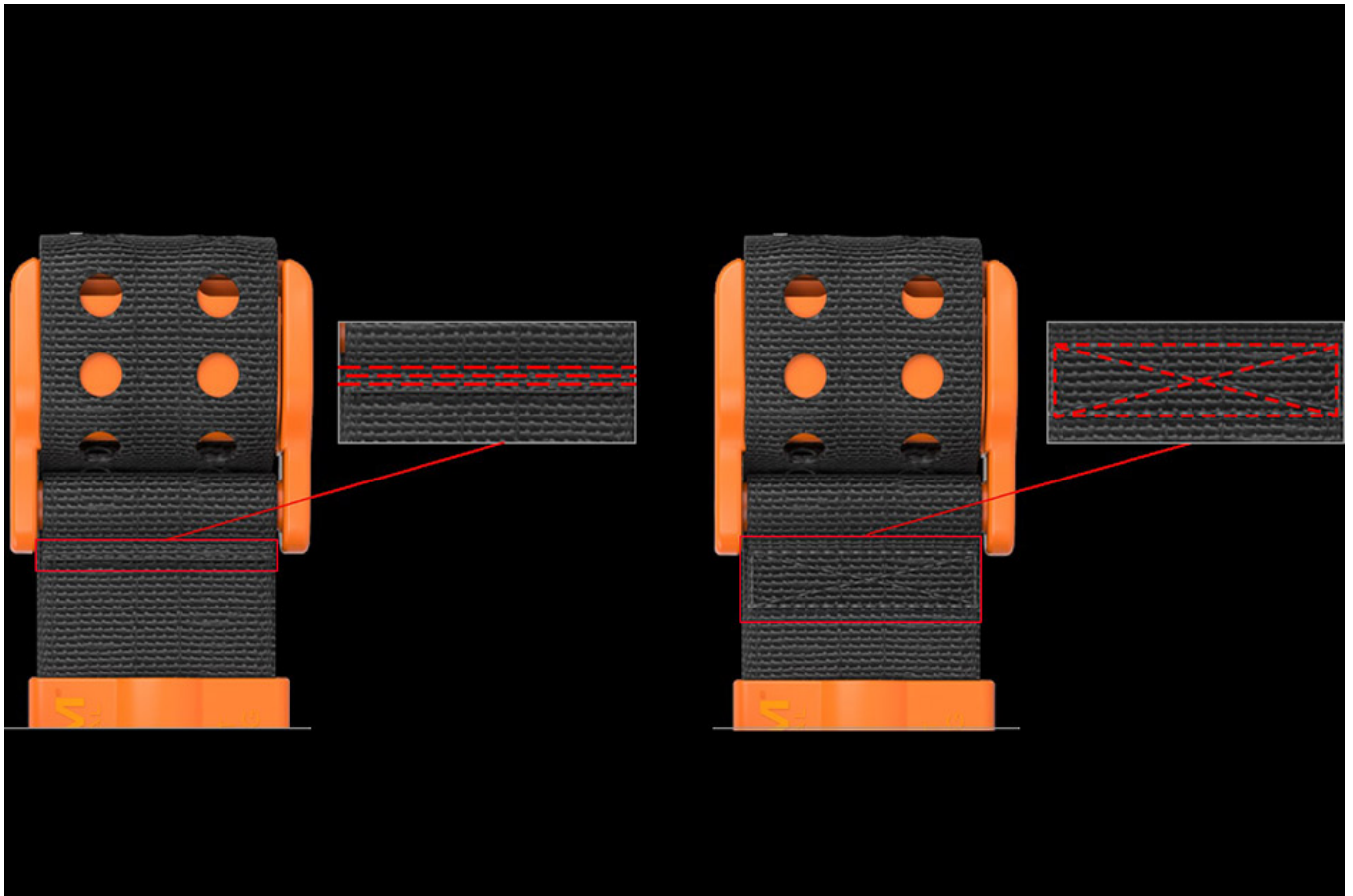
Only a small number of lots are being recalled. This product has been sold worldwide since March 2017. No other types of tourniquets are affected.

The SAM XT devices affected by the recall can be identified by:

- The absence of a “Box X Stitch” on the Instructions For Use (IFU)



- The absence of a “Box X Stitch” on the device



- Any Lot Number with XT1812 or higher



John Wilkinson, the Medicines and Healthcare products Regulatory Agency's

(MHRA) Director of Medical Devices, said:

Check if you have the listed tourniquet and if you do so, please separate the device from your pack and take them back to where you bought them from.

Our highest priority is making sure medical devices are safe. This is why we are supporting the company to carry out this recall and why we want people to check their inventory.

As with any medical device, we strongly encourage anyone to report any suspected manufacturing faults to us via our Yellow Card Scheme.

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2. [Link to Yellow Card Scheme](#)
3. [Medical Device Alert](#)
4. [SAM Medical company website recall](#)

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## Press release: UK steps up fight against Ebola following outbreak in Democratic Republic of Congo

The UK is backing the World Health Organisation's (WHO's) Regional Preparedness Plan to support nine countries at high risk of receiving cases of Ebola from their neighbour, the Democratic Republic Congo (DRC).

UK aid's £1.5m of support will enable WHO to support countries with prevention, detection and containment of Ebola and other deadly diseases. It will also help important work being done at the community level, such as working with traditional healers, health workers and religious leaders around issues including safe and dignified burials. This will lead to an increased number of referrals of those with symptoms in harder to reach areas.

This new funding will help stop the immediate spread of the current DRC outbreak as well as build longer term resilience and follows significant support already committed by the International Development Secretary Penny Mordaunt in May. To date, the UK response has helped to stabilise the outbreak, but the threat of it spreading to other countries remains.

Minister for Africa, Harriett Baldwin said:

The UK continues to act decisively to stop this outbreak of Ebola, an horrific contagious disease which has the potential to cause devastating loss of life.

By supporting the WHO's Regional Preparedness Plan, UK aid will help to scale up preparedness to ensure sustainability. We are not just waiting for the next outbreak to come along, but are actively working in partnership around the world to strengthen health systems. This is keeping us all safe from current and future global health emergencies.

The UK has the resources and know-how to help contain the spread of epidemics, but there is still work to do. Outbreaks are inevitable but epidemics are preventable.

Dr Ibrahima-Soce Fall, WHO Regional Emergencies Director, said:

Investing in preparedness is crucial to keep the world safe from Ebola. WHO is grateful for this additional funding from UK aid, which will support nine countries to better prevent, detect and respond to this deadly virus.

The UK continues to be a global leader in the fight against deadly diseases like Ebola and support to WHO reform in Africa has helped bring about a swifter and better-coordinated response to the outbreak in the DRC, a sharp contrast to the 2014 Ebola outbreak in Sierra Leone.

## Notes to Editors

- WHO's Regional Preparedness and Readiness Plan aims to fill gaps identified by recent assessments. The estimated budget for the plan (June 2018 – February 2019) is US\$15.5m over nine months. The plan is divided into two phases of priority actions. Phase I will be implemented in the next three months and will bolster operational readiness should there be any importation of Ebola cases. Phase II will look at the scale up of preparedness actions to ensure sustainability over the longer term.
- This £1.5 million of new funding support is taken from DFID's Crisis Reserve, and is being provided immediately to the World Health Organisation's response plan for at least the next three months.
- It comes after a previous £5 million support was provided to the World Health Organisation's response plan in May 2018.
- The Crisis Reserve funding is in addition to £1 million which DFID made available from its joint research initiative on epidemic preparedness with Wellcome. Wellcome has also made a further £2 million available to deal with the Ebola outbreak, which is being used to help roll out the vaccine campaign.
- The UK's response to Ebola in 2014 represented a great success in preventing the spread of a killer disease that threatened to reach 1.4 million cases. However, it came at significant cost to the UK taxpayer and African economies which lost at least \$1.6 billion. Following previous DFID programmes (Regional Preparedness Programme and the Regional Malaria Programme, notably) the new Tackling Deadly Diseases in Africa Programme (TDDAP) aims to save lives and reduce the impact of disease outbreaks on African populations. This includes support to the reform of WHO in the Africa region, where it is already showing progress through swifter, better-coordinated outbreak responses in the DRC and Madagascar.
- Investing in health systems early is important and good value for money, because it enhances the world's ability to prevent epidemics, rather than reacting to the next crisis. Evidence suggests that for every £1 invested in preparation a £2 return can be achieved in terms of savings

on future spending and investments.

- Public Health England has assessed the risk of this outbreak to the UK as negligible to very low.

## General media queries

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## [Press release: PHE and Disney UK launch Change4Life Train Like A Jedi programme](#)

The new [Change4Life Train Like a Jedi programme](#) uses the excitement of Star Wars™ and its characters – alongside Double Olympic Gold medallist Jade Jones – to encourage children to Train Like A Jedi and is designed to increase levels of physical activity amongst children in England.

It is recommended that children do at least 60 minutes of moderate to vigorous physical activity every day, yet just 23% of boys and 20% of girls aged 5 to 15 years currently meet this recommendation.

This year marks the fifth year PHE and Disney have worked together to inspire children to move more, with an estimated 300 million minutes of activity inspired to date.

A new survey from PHE and Disney found that over 4 in 5 children (82%) would be inspired to move more if they saw their favourite characters being active. With Star Wars characters ranking as key favourites amongst UK children aged 7 to 11, the programme aims to make physical activity fun and inspire children to move more.

In addition, the survey from PHE and Disney looking at the factors that influence children to be more active found:

- 59% of children say they would be more active if exercise felt fun



- children (58%) and parents (55%) ranked friends as the most influential figure in encouraging children to be more physically active
- 99% of children say they enjoy doing physical activity or sports with their parent or carer

Building a new generation of 'Resistance' recruits, British taekwondo athlete and double Olympic gold medallist Jade Jones, alongside a special appearance from BB-8, leads children through a series of Jedi-inspired moves in an exciting new play-along video.

Taking inspiration from the traits of iconic Jedi such as Luke Skywalker and Rey, Train like A Jedi helps children learn and master 6 key skills – technique, strength, stamina, speed, agility and mastery. The sequence of moves has been specially designed to increase children's heart rates and benefit health.

The video is designed for children to play along anywhere – either in groups, with their friends, family, or by themselves – and will help children meet the daily recommended physical activity guidelines they need for healthy development and to maintain a healthy weight. The Train Like A Jedi activity can be done in 10-minute bursts throughout the day.

In addition to the video, the campaign will include regional events, advertising, social media activity and a free Star Wars themed pack with mini active challenges for the summer holidays. Packs will be made available through primary schools before the summer holidays.

Eustace de Sousa, National Lead for Children at Public Health England said:

Children's physical activity levels are alarmingly low and are having a major impact on their physical and mental health – both now and into adulthood.

Getting into the habit of being regularly active will have lifelong benefits. Our Change4Life Train Like A Jedi programme is a great way for children, their friends and the whole family to get moving throughout the summer.

Double Olympic gold medallist Jade Jones comments:

Inspiring kids to get active is something I'm really passionate about, so I was thrilled to get the opportunity to help kids across the country with Change4Life and Star Wars.

It was great fun to create the Jedi-inspired moves which can be done anytime and anywhere – both at school and home. I hope that through this new programme we can inspire a new generation to move more by showing kids that physical activity can be really fun.

Mark Hamill, the actor best known for his portrayal of Luke Skywalker, offered his support to children taking part with some video messages, saying:

If you want to become a Jedi like Luke Skywalker or Rey, then you need to be fit, healthy and strong.

This summer, Change4Life can help you Train Like A Jedi. May the Force be with you.

Marianthi O'Dwyer, Vice President, Healthy Living, The Walt Disney Company UK, comments:

Using Star Wars characters and storytelling, we can help encourage children to be active by making it fun. With the huge popularity of Star Wars amongst UK kids aged 7 to 11, we believe this campaign will encourage children to get out and move like Jedi!

This is another great example of Disney's healthy living commitment in action, where we use Disney's characters and stories to encourage families and children to be more active together.

Last year, PHE and Disney helped more than 2 million children aged 3 to 11 get active with the 10 Minute Shake Up programme. This year, the Change4Life Train Like A Jedi programme will build on this success with all-new ways of getting children's hearts pumping.

In the same way that mentorship plays a pivotal role for Jedi, schools have a major influence on children's physical activity levels. Change4Life will provide schools with curriculum-linked teacher resources, including a Train Like A Jedi training video, to encourage their pupils to learn the Jedi-inspired moves and be active both in and outside the classroom.

The [Change4Life Train Like A Jedi programme](#) is also supported by Sport England.

## **Public Health England press office**

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## Background

The Opinium survey for Public Health England and Disney questioned 1,263 parents of children aged 5 to 11 in England and 783 children aged 5 to 11 in England about their attitudes to physical activity and took place in April 2018.

### About Change4Life

[Change4Life](#) is PHE's flagship social marketing programme which aims to help families to eat well and move more. PHE exists to protect and improve the nation's health and wellbeing and reduce health inequalities. It does this through advocacy, partnerships, world-class science, knowledge and intelligence, and the delivery of specialist public health services. [PHE](#) is an operationally autonomous executive agency of the Department of Health. Follow us on Twitter @PHE\_uk.

### About Disney's Healthy Living Commitment

In 2006, The Walt Disney Company made a global commitment to support parents and create healthier families by using its stories and characters to make healthy living simple and fun. Since 2006, Disney has been offering different ways to support families to live more healthily. This includes introducing robust nutritional guidelines for food and drinks as well as their advertising, offering content that positively focuses on healthier lifestyles such as Disney Channel's First Class Chefs, The Lodge and Aim High, and inspiring activity and healthier eating through programmes such as Change4Life '10 Minute Shake Up', PHE, Disney and Swim England 'Just Keep Swimming' Finding Dory programme, the partnership with the Football Association and Girls' Football Week, and Disney's #HealthilyEverAfter marketing campaign.

### About The Walt Disney Company UK & Ireland

The Walt Disney Company, together with its subsidiaries and affiliates, is a leading diversified international family entertainment and media enterprise. Disney is a Dow 30 company and had annual revenues of \$55.1 billion in its last fiscal year (FY17).

The Walt Disney Company has operated in the UK and Ireland for over 80 years, employing more than 3,300 people, and is dedicated to creating innovative, entertainment experiences for children and families. The Disney brand is experienced in a number of ways across the UK and Ireland including in cinemas, on stage, via its streaming app DisneyLife, on TV screens with Disney-branded channels and through a wide range of consumer products that are sold at mass market retailers and in Disney Stores. Now in its fifth year, Disney's partnership with Public Health England and the '10 Minute Shake Up' campaign has seen over 2 million kids get active with an estimated 300 million extra minutes of physical activity being completed.

## About Sport England

Sport England is a public body and invests more than £300 million National Lottery and government money each year in projects and programmes that help people get active and play sport. It wants everyone in England, regardless of age, background, or level of ability, to feel able to engage in sport and physical activity. That's why a lot of its work is specifically focused on helping people who do no, or very little, physical activity and groups who are typically less active – like women, disabled people and people on lower incomes.

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